

Line Listing Report

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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country (as per report)	Literature Reference	Patent Age (Days)	Patent Age (as per report)	Patent Status	Patent Report	Reaction List (Duration 7 Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
EU-EC-100098078	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (5d - Unknown - Caused/Prolonged Hospitalisation), Hospice care (3d - Unknown -), Pneural effusion (n/a - Unknown - Other Medically Important Condition), Pneumonia (5d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098104	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 5mL - Intramuscular])	Not reported	ICSR	
EU-EC-100098105	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098521	03/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - (1d - 1DP) - Intramuscular)	Not reported	ICSR	
EU-EC-1000988152	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100098806	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Bleiser (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098172	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098017	03/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	AMMONIUM LACTATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE (C - Bipolar disorder - n/a - [n/a - 20mg - Oral]), DOUCABATE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FLECAIANDE, FLECAIANDE ACETATE (C - Atrial fibrillation - n/a - [n/a - 100mg - Oral]), HYDROMORPHONE HYDROCHLORIDE (C - Pain - n/a - [n/a - 4mg - Oral]), LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MAGNESIUM, 3366 (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SALBUTAMOL, SALBUTAMOL SULFATE (C - Chronic obstructive pulmonary disease - n/a - [n/a - 7.5mg - n/a]), VALPROIC ACID (C - Depression - n/a - [n/a - 500mg - n/a])	Not reported	ICSR
EU-EC-100098697	02/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Chills (n/a - Unknown -), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Lethargy (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098137	02/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (12d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098828	02/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098870	02/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098943	02/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Vaccination site oedema (n/a - Unknown -), Vaccination site pain (n/a - Unknown -), Vaccination site swelling (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098751	02/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Cardiomegaly (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Palpitations (n/a - Fatal - Results in Death), Product administered to patient of inappropriate age (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098209	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 pneumonia (171d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098218	01/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dermatitis (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098280	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Confusional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098274	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Adrenaline desaturation (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098358	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Abdominal distension (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Ocular hyperaemia (n/a - Fatal - Results in Death), Purpura (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), SHINGRIX (RECOMBINANT VARICELLA ZOSTER VIRUS GLYCOPROTEIN E, STIMULON, MONOPHOSPHORYL LIPID AC) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DOLCALCIFEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SOLIFENACIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [VALPROIC ACID] (C - Product used for unknown indication - n/a - [n/a - 125mg - Unknown])	Not reported	ICSR
EU-EC-100098404	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098406	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (70d - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	ALLIUM SATIVUM (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM CARBONATE, CALCIUM GLUBONATE, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [BIMASTATINE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [TROPICAM, TROPICAM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [ARIPRAZOLE (ARIPRAZOLE)] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [METHOTREXATE (METHOTREXATE)] (C - Product used for unknown indication - n/a - [n/a - 2.5mg - Unknown]), [ISOSORBIDE MONONITRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LAMOTRIGINE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [MELOXICAM] (C - Product used for unknown indication - n/a - [n/a - 7.5mg - Unknown]), [DMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [PRAZOSIN] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), [ZOLPIDEM TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown])	Not reported	ICSR
EU-EC-100098423	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098450	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Cardiac arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 15DP] - Unknown)	Not reported	ICSR	
EU-EC-100098407	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown -), SARS-CoV-2 test positive (4d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098454	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Aphasia (33d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Bacteremia (33d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Central venous catheterisation (33d - Fatal - Results in Death), Death (33d - Fatal - Results in Death, Other Medically Important Condition), Disease recurrence (33d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (33d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Gait instability (33d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (33d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Purpura (33d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Persistent swelling (33d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM CARBONATE, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM (C - Supplementation therapy - n/a - [n/a - n/a - Unknown]), [DOLCALCIFEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-100098578	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (190d - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), General physical health deterioration (190d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098502	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	NOT AVAILABLE (C - n/a - Not applicable -), ACEFOLCALCIC ACID (C - n/a - Not applicable -), FUROSEMIDE (C - n/a - Not applicable -), LOSARTAN, LOSARTAN POTASSIUM (C - n/a - Not applicable -), MEMENTAN HYDROCHLORIDE (C - n/a - Not applicable -), [PARACETAMOL] (C - n/a - Not applicable - [n/a - 1000mg - n/a]), [DIETILPINE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [BIMASTATINE] (C - n/a - Not applicable -), [SOTALOL HYDROCHLORIDE] (C - n/a - Not applicable - [n/a - 40mg - n/a])	Not reported	ICSR
EU-EC-100098563	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COVID-19 (5d - Fatal - Results in Death), Death (5d - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (5d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098622	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Intra-aortic perfusion (24d - Fatal - Results in Death, Other Medically Important Condition), Sepsis (24d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098679	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	BENZONATE (C - Cough - n/a - [n/a - 600mg - n/a]), FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [GLIPZIDE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), METHFORMIN, METHFORMIN HYDROCHLORIDE, METHFORMIN HYDROCHLORIDE BIP (C - Product used for unknown indication - n/a - [n/a - 2000mg - n/a]), [PANTOPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), [SPRONOLACTONE] (C - Product used for unknown indication - n/a - [n/a - 50mg - Unknown])	Not reported	ICSR
EU-EC-100098682	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098624	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cerebral haemorrhage (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098680	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098187	01/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (13d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098210	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Carbon monoxide poisoning (n/a - Fatal - Results in Death), Cervical vertebral fracture (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Rib fracture (n/a - Fatal - Results in Death), Spinal cord haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098280	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098327	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (13d - Fatal - Results in Death), Cerebral haemorrhage (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dizziness (13d - Fatal - Results in Death), Fall (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098384	31/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fall (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000984216	31/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (2d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098414	31/08/2													

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Route)	CSR Form	
			Professional	Non European Economic Area	Not available	Years	Specified			Death (via - Fatal - Results in Death, Other Medically Important Condition)	VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Unknown - [via - 1DF] - Intramuscular)			
EU-EC-100098106	30/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Hospitalisation (7d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	CSR	
EU-EC-1000980694	27/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Aortic aneurysm (1d - Fatal - Results in Death), Aortic aneurysm rupture (1d - Fatal - Results in Death, Other Medically Important Condition), Atherosclerosis (1d - Fatal - Results in Death), Asthma (1d - Fatal - Results in Death), Atrial fibrillation (1d - Fatal - Results in Death, Other Medically Important Condition), Back pain (1d - Fatal - Results in Death), Cardio-respiratory arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Hypertensive heart disease (1d - Fatal - Results in Death), Hypertension (1d - Fatal - Results in Death), Nausea (1d - Fatal - Results in Death), Reperforated haematoma (1d - Fatal - Results in Death, Other Medically Important Condition), Syncopal (1d - Fatal - Results in Death, Other Medically Important Condition), Tachycardia (1d - Fatal - Results in Death), Vomiting (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	CSR	
EU-EC-10009807157	27/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anemia (via - Unknown - Caused/Prolonged Hospitalisation), Clavicle fracture (via - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fat (via - Unknown - Caused/Prolonged Hospitalisation), Generalised oedema (via - Unknown - Caused/Prolonged Hospitalisation), Hyperkalemia (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Subcutaneous haematoma (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	CSR	
EU-EC-10009814302	27/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Adverse event (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	CSR	
EU-EC-1000981589	27/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	CSR	
EU-EC-10009817548	27/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Adverse event (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	CSR	
EU-EC-1000976884	26/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Asthma (10d - Fatal - Results in Death, Other Medically Important Condition), Chest discomfort (10d - Fatal - Results in Death, Other Medically Important Condition), Cough (10d - Fatal - Results in Death, Other Medically Important Condition), Death (0d - Fatal - Results in Death, Other Medically Important Condition), Dizziness (10d - Fatal - Results in Death, Other Medically Important Condition), Hypertension (10d - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (0d - Fatal - Results in Death, Other Medically Important Condition), Myocardial ischaemia (0d - Fatal - Results in Death, Other Medically Important Condition), Phytosis (10d - Fatal - Results in Death, Other Medically Important Condition), Rhinorrhoea (10d - Fatal - Results in Death, Other Medically Important Condition)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - via - [via - 1DF] - Intramuscular)	OLANZAPINE (OLANZAPINE) (C - via - via - [via - n/a - Oral], VICTOZA (LIRAGLUTIDE) (C - via - via - [via - n/a - n/a])	CSR	
EU-EC-10009792079	26/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Congestion aggravated (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (0d - Unknown - Caused/Prolonged Hospitalisation), Death (0d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic encephalopathy (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Toxicity to various agents (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	DEXAMETHASONE (DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE) (C - Product used for unknown indication - via - [via - n/a - n/a]), DOXYCYCLINE DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE) (C - Product used for unknown indication - via - [via - n/a - n/a]), (FAMOTIDINE) (C - Product used for unknown indication - via - [via - n/a - n/a]), (METHANOL) (C - Product used for unknown indication - via - [via - n/a - n/a]), (DAYSIN) (C - Product used for unknown indication - via - [via - n/a - n/a]), (SALBUTAMOL SULFATE) (C - Product used for unknown indication - via - [via - n/a - n/a])	CSR	
EU-EC-10009802654	26/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Adult	Male	No	Death (via - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [1d - 1DF] - Intramuscular)	Not reported	CSR
EU-EC-10009804291	26/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardio-respiratory arrest (via - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (via - Unknown - Other Medically Important Condition), Cranial nerve disorder (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (via - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (via - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Missed dose (via - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	CSR	
EU-EC-10009804634	26/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	CSR	
EU-EC-10009806746	26/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), White blood cell count increased (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	ACETYLSALICYLIC ACID, CAFFEINE) (C - Product used for unknown indication - via - [via - n/a - n/a]), (MACROGOL 3350) (C - Product used for unknown indication - via - [via - n/a - n/a]), (MONTELUKAST, MONTELUKAST SODIUM) (C - Product used for unknown indication - via - [via - n/a - n/a]), (DIMEPRIZOLE) (C - Product used for unknown indication - via - [via - n/a - n/a]), (SERTRALINE, SERTRALINE HYDROCHLORIDE) (C - Product used for unknown indication - via - [via - n/a - n/a])	CSR	
EU-EC-10009807121	26/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Atherosclerosis (via - Fatal - Results in Death), Cardiac failure congestive (via - Fatal - Results in Death, Other Medically Important Condition), Coronary artery disease (via - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Immediate post-injection reaction (via - Fatal - Results in Death), Malaise (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	CSR	
EU-EC-10009782199	25/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cerebral thrombosis (307h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (130min - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary thrombosis (307h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (307h - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	CSR	
EU-EC-10009782654	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Endotracheal intubation (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Product administered at inappropriate site (via - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Subcutaneous)	Not reported	CSR	
EU-EC-10009783298	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chest pain (3d - Fatal - Results in Death, Other Medically Important Condition), Death (3d - Fatal - Results in Death, Other Medically Important Condition), Fat (3d - Fatal - Results in Death), Life support (3d - Fatal - Results in Death), Organ donor (3d - Fatal - Results in Death), Syncope (3d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	(ATORVASTATIN) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (SABAFENTIN) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (HYDROXYZINE EMBONATE) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (LISINAPRIL, LISINAPRIL DIHYDRATE) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (METHOCARBAMOL) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (NETOPROLOL, NETOPROLOL) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (PREDNISONE) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (SALBUTAMOL SULFATE) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (TRAZODONE, TRAZODONE HYDROCHLORIDE) (C - Product used for unknown indication - via - [via - n/a - Unknown])	CSR	
EU-EC-10009783422	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular - More in CSR)	Not reported	CSR	
EU-EC-10009783466	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Asthma (via - Not Recovered/Not Resolved -), Back pain (via - Not Recovered/Not Resolved -), Burning sensation (via - Not Recovered/Not Resolved -), Cardiac failure (via - Fatal - Results in Death, Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (via - Not Recovered/Not Resolved -), Gait inability (via - Not Recovered/Not Resolved -), General physical health deterioration (via - Not Recovered/Not Resolved -), Malaise (via - Not Recovered/Not Resolved -), Memory impairment (via - Not Recovered/Not Resolved -), Pain (via - Not Recovered/Not Resolved -), Rash (via - Not Recovered/Not Resolved -), Thinking abnormal (via - Not Recovered/Not Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular - More in CSR)	Not reported	CSR	
EU-EC-10009784162	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	COVID-19 (146d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (via - Fatal - Results in Death, Other Medically Important Condition), Death (146d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (146d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (146d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	CSR	
EU-EC-10009784710	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Amyotonia (via - Fatal - Results in Death, Other Medically Important Condition), Aspiration (via - Fatal - Results in Death, Other Medically Important Condition), Bladder catheterisation (via - Fatal - Results in Death), COVID-19 (via - Fatal - Results in Death), Cerebral small vessel ischemic disease (via - Fatal - Results in Death, Other Medically Important Condition), Chronic sinusitis (via - Fatal - Results in Death), Coma scale (via - Fatal - Results in Death), Computerized tomogram head abnormal (via - Fatal - Results in Death), Death (via - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (via - Unknown -), Endotracheal intubation (via - Fatal - Results in Death), Pulse absent (via - Fatal - Results in Death), Pulseless electrical activity (via - Fatal - Results in Death, Other Medically Important Condition), Respiratory distress (via - Fatal - Results in Death, Other Medically Important Condition), Resuscitation (via - Fatal - Results in Death), SIDS (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	DEXAMETHASONE (DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE) (C - Product used for unknown indication - via - [via - n/a - n/a])	CSR	
EU-EC-10009784881	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (169d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (169d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (169d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Gastrointestinal haemorrhage (169d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	CSR	
EU-EC-10009784912	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 pneumonia (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (via - Unknown -), Inappropriate schedule of product administration (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	CSR	
EU-EC-10009785223	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (17d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	CSR	
EU-EC-10009785663	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	COVID-19 pneumonia (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (via - Unknown -), Vaccine breakthrough infection (23d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	CSR	
EU-EC-10009786072	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Septic syndrome (via - Fatal - Results in Death, Other Medically Important Condition), Cardio-respiratory arrest (via - Fatal - Results in Death, Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Pnyxia (via - Fatal - Results in Death), Revascularisation (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	HEPPIA (LEVITRACETAM) (C - Product used for unknown indication - via - [via - n/a - Unknown]), LANTIS (PULSIN, GLIBENCLAMIDE) (C - Product used for unknown indication - via - [via - n/a - Unknown]), ACETYLSALICYLIC ACID) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (AMLODIPINE, AMLODIPINE BESILATE) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (ASCORBIC ACID) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (CASSIA, CASSIA SENNA WHOLE, HYDROXYANTHRACENE GLYCOSIDES, SENNA PODS, SENNOSIDE B, SENNOSIDE) (C - Product used for unknown indication - via - [via - 1DF] - Unknown), (MACROGOL 3350) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (VALPROIC ACID) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (ZINC) (C - Product used for unknown indication - via - [via - n/a - Unknown])	CSR	
EU-EC-10009786162	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Lymphadenopathy (175d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lymphedema (175d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular - More in CSR)	Not reported	CSR	
EU-EC-10009786266	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	CSR	
EU-EC-10009787023	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Anticoagulant therapy (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal infarct (48d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	(ATORVASTATIN) (C - Product used for unknown indication - via - [via - n/a - Unknown]), (METOPROLOL, METOPROLOL TARTRATE) (C - Product used for unknown indication - via - [via - n/a - Unknown])	CSR	
EU-EC-10009787283	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebral haemorrhage (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dementia (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	CSR	
EU-EC-10009787712	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (via - Recovered/Resolved -), Dysphagia (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (via - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (via - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular - More in CSR)	Not reported	CSR	
EU-EC-10009787761	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (11d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	CSR	

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country (as per Regulatory Purpose)	Literature Reference	Age Group (as per reporter)	Sex	Parent Child	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
EU-EC-1000791962	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Sepsis (1mo - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (1mo - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 100mg] - Unknown - More in CSR)	APIXIBAN (APIXIBAN) (C - Product used for unknown indication - n/a - [19d - 10mg] - Unknown), DUALAGLUTIDE (DUALAGLUTIDE) (C - Product used for unknown indication - n/a - [19d - 10mg] - Unknown), INSULIN GLARGINE (INSULIN GLARGINE) (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), INSULIN LISPRO (INSULIN LISPRO) (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [19d - 81mg] - Unknown), AMOXICILLIN AMOXICILLIN TRIHYDRATE (C - Product used for unknown indication - n/a - [19d - 1000mg] - Unknown), BISOPROLOL BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE (C - Product used for unknown indication - n/a - [19d - 10mg] - Unknown), DOLECALCIFEROL (C - Product used for unknown indication - n/a - [19d - 2000DF] - Unknown), FUROSEMIDE (C - Product used for unknown indication - n/a - [19d - 20mg] - Unknown), [THAMINE, PYRIDOXINE HYDROCHLORIDE, VITAMIN B] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown)	CSR
EU-EC-1000798275	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Male	COVID-19 (8d - Fatal - Results in Death), Cough (8d - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (1d - Recovered/Resolved -), Myalgia (8d - Fatal - Results in Death), Pyrexia (8d - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 100mg] - Unknown)	Not reported	CSR
EU-EC-1000798469	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Male	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 100mg] - Unknown)	Not reported	CSR
EU-EC-1000799215	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (31d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 100mg] - Unknown)	ACETYLSALICYLIC ACID, ACETYLSALICYLIC ACID PH. EUR., ASPIRIN BR] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [ASCORBIC ACID] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [DIMETICONE, ZINC OXIDE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [FERRUS SULFATE] (C - n/a - [19d - n/a] - Unknown), [KETOCOAZOLE, KETOCOAZOLE PH. EUR.] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [MACRODOL, 400, MACRODOL, PROPYLENE GLYCOL, MACRODOL, PROPYLENE GLYCOL, MACRODOL, 400] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [METFORMIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [NEOMYCIN SULFATE, POLYMYXIN B SULFATE, DEXAMETHASONE, NEOMYCIN SULFATE, POLYMYXIN B, DEXAMETHASONE, NEOMYCIN, POLYMYXIN B SULFATE, DEXAMETHASONE, NEOMYCIN, POLYMYXIN B, DEXAMETHASONE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [DXYBUTYNN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [PARACETAMOL] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [RISPERIDONE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [TAMBOLOGIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [URSARANE] (EMBUGLIFLOZIN) (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [ATENOLOL, ATENOLOL BP] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - Neurgaia - n/a - [19d - n/a] - Unknown)	CSR
EU-EC-1000791030	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Anxiety (57d - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (57d - Fatal - Results in Death), Impaired driving ability (57d - Fatal - Results in Death), Malaise (57d - Fatal - Results in Death), Night sweats (57d - Fatal - Results in Death), Pain (57d - Fatal - Results in Death), Sarcoma (57d - Fatal - Results in Death, Other Medically Important Condition), White blood cell count increased (57d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 100mg] - Unknown)	Not reported	CSR
EU-EC-1000791050	25/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	Chest discomfort (19d - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (19d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 100mg] - Unknown)	Not reported	CSR
EU-EC-10007918471	24/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Asthma (19d - Unknown - Caused/Prolonged Hospitalisation), Confusional state (19d - Unknown - Caused/Prolonged Hospitalisation), Death (19d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (19d - Unknown -), Gastrointestinal haemorrhage (74d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemoglobin decreased (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Heart rate increased (19d - Unknown - Caused/Prolonged Hospitalisation), Hypertension (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), International normalised ratio increased (19d - Unknown - Caused/Prolonged Hospitalisation), Lethargy (19d - Unknown -), Tinnitus (19d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 100mg] - Unknown)	CYCLOBENZAPRINE, CYCLOBENZAPRINE HYDROCHLORIDE (C - Muscle spasm - n/a - [19d - 10DF] - Unknown), HYDROCODONE BITARTRATE, PARACETAMOL (C - Back pain - n/a - [19d - 10DF] - Unknown), [WARFARIN, WARFARIN SODIUM] (C - Deep ven thrombosis - n/a - [19d - 10DF] - Oral)	CSR
EU-EC-1000774965	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (19d - Fatal - Results in Death)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [1d - 5mL - Intramuscular])	Not reported	CSR
EU-EC-1000791508	24/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Death (19d - Fatal - Results in Death)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [1d - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-1000791476	23/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (0d - Fatal - Results in Death), Pyrexia (19d - Unknown -), Death (19d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 100mg] - n/a)	PARACETAMOL (C - Pyrexia - n/a - [19d - 1000mg] - n/a)	CSR
EU-EC-1000791511	23/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (19d - Unknown -), Headache (19d - Unknown -), Illness (19d - Unknown -), Influenza like illness (19d - Unknown -), Mildly depressed (19d - Unknown -), Death (19d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - n/a)	Not reported	CSR
EU-EC-1000791080	21/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (19d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-10007912067	20/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Abdominal pain (19d - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (19d - Unknown - Caused/Prolonged Hospitalisation), Death (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (19d - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (19d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (19d - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Unknown)	Not reported	CSR
EU-EC-10007914277	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Blood pressure increased (3d - Recovered/Resolved -), Death (19d - Fatal - Results in Death), Decreased appetite (19d - Unknown -), Dyspnoea (19d - Unknown -), Fatigue (19d - Unknown -), Hyperhidrosis (19d - Unknown -), Injection site pain (2d - Recovered/Resolved -), Syncope (19d - Unknown -)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - Immunisation - Not applicable - [19d - 5mL - Intramuscular])	ACETYLSALICYLIC ACID (C - n/a - Dose not changed - [19d - 100mg] - Oral), [AMLODIPINE, BISOPROLOL] (C - Essential hypertension - Dose not changed - [19d - n/a] - Oral), [ATORVASTATIN] (C - n/a - Dose not changed - [19d - 20mg] - Oral), [METFORMIN] (C - Type 2 diabetes mellitus - Dose not changed - [19d - 1000mg] - Oral)	CSR
EU-EC-1000794835	20/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Acute respiratory distress syndrome (19d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-1000791781	20/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Pharyngitis (19d - Fatal - Results in Death, Other Medically Important Condition), Death (19d - Fatal - Results in Death), Vaccination site erythema (19d - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-10007918623	20/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Cardiac disorder (19d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cranial nerve disorder (19d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (19d - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (19d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-10007918198	20/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (19d - Fatal - Results in Death, Other Medically Important Condition), Dysphonia (2d - Fatal - Results in Death), Dyspnoea (1d - Fatal - Results in Death), Oropharyngeal pain (2d - Fatal - Results in Death), Poliakulitis (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-10007927523	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Acute hepatic failure (19d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (19d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemophagocytic lymphohistiocytosis (19d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperthermia (19d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aggradis (19d - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pruritus (19d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sleep disorder (19d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Unknown)	DEICITABINE [DEICITABINE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), MELATONIN [MELATONIN] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [ALLOPURINOL] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [COLICALCIFEROL] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [FLECANIDE, FLECANIDE ACETATE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [FOLIC ACID] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [MAGNESIUM OXIDE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [OMEPRAZOLE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [PENTAMIDINE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [VALACICLOVIR] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown)	CSR
EU-EC-1000792820	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Asthma (42d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Blood test (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac failure congestive (42d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (42d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (42d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea exertional (42d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (42d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Leukemia (42d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Peripneal swelling (42d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Walking aid user (42d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-1000792932	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (14d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Unknown)	METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [19d - 10DF] - Unknown)	CSR
EU-EC-10007929913	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	Abdominal pain upper (1d - Fatal - Results in Death), Candidis (1d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Inflammation (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [PYRIDOXINE HYDROCHLORIDE, VITAMIN B] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown)	CSR
EU-EC-10007930130	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (1d - Fatal - Results in Death), Somnolence (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Unknown)	[ALPRAZOLAM] (C - Product used for unknown indication - n/a - [19d - 5mg] - Unknown), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [19d - 40mg] - Unknown), [DXYCODONE, DXYCODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [19d - 25mg] - Unknown), [PROMETHAZINE, PROMETHAZINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [19d - 25mg] - Unknown), [SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [19d - n/a] - Unknown), [TURMERIC] (C - Product used for unknown indication - n/a - [19d - 500mg] - Unknown), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [19d - 37.5mg] - Unknown)	CSR
EU-EC-1000793464	19/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	Death (19d - Fatal - Results in Death)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-1000793503	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	Death (19d - Fatal - Results in Death)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - n/a)	[ALLOPURINOL] (C - Gout - n/a - [19d - n/a] - n/a), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [19d - n/a] - n/a), [SIMVASTATIN] (C - Blood cholesterol increased - n/a - [19d - n/a] - n/a), [TESTOSTERONE] (C - Blood testosterone decreased - n/a - [19d - n/a] - n/a)	CSR
EU-EC-1000791052	19/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-10007918117	19/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Athralgia (19d - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Erythema (19d - Unknown - Other Medically Important Condition), Feeling hot (19d - Unknown - Other Medically Important Condition), Headache (19d - Unknown -), Hematuria (19d - Unknown -), Illness (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (19d - Unknown - Other Medically Important Condition), Mobility decreased (19d - Unknown - Other Medically Important Condition), Nausea (19d - Unknown -), Pain in extremity (19d - Unknown - Other Medically Important Condition), Peripneal swelling (19d - Unknown - Other Medically Important Condition), Pneumonia (19d - Unknown - Other Medically Important Condition), Pyrexia (19d - Unknown -), Sepsis (19d - Fatal - Results in Death, Other Medically Important Condition), Urinary tract infection (19d - Unknown - Other Medically Important Condition), Vaccination complication (19d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	[CASSIA] (C - Abdominal discomfort - n/a - [19d - 12.2mg] - Unknown), [DOBUSATE SODIUM] (C - Abdominal discomfort - n/a - [19d - 100mg] - Unknown), [HYDRALAZINE] (C - Hypertension - n/a - [19d - 100mg] - Oral), [SODIUM BICARBONATE] (C - Cardiac arrest - n/a - [19d - 60mg] - Unknown)	CSR
EU-EC-10007916919	18/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-10007917480	18/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Intramuscular)	Not reported	CSR
EU-EC-10007919116	18/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	COVID-19 (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (19d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [19d - 10DF] - Unknown)	Not reported	CSR

EU Local Number	EV Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Age Group	Sex	Outcome	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Subspecting Drug List (Drug Char - Indication PT - Action taken - Duration - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form		
EU-EC-100071944	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	[LISDEXAMFETAMINE DIMESYLATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	ICSR	
EU-EC-100071961	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072029	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072023	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Mental status changes (14d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072035	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072041	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (27d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072052	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Male	No	COVID-19 (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072130	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Malaise (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072192	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (2d - Fatal - Results in Death, Other Medically Important Condition), Otitis (2d - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (2d - Fatal - Results in Death, Other Medically Important Condition), Nausea (2d - Fatal - Results in Death), Panic attack (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072123	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	VITAMIN D3 (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	ICSR	
EU-EC-100072327	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072327	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072364	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (8d - Fatal - Results in Death, Other Medically Important Condition), Hepatic encephalopathy (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072615	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072624	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cerebrovascular accident (6d - Fatal - Results in Death, Other Medically Important Condition), Coma (6d - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (6d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100072618	15/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Apnoea (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiorespiratory (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Revascularisation (n/a - Fatal - Results in Death), Snoring (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	TRAJENTA [NAGLIPPTIN] (C - Product used for unknown indication - n/a -), TREBIA [INSULIN DEGLUCOSE] (C - Product used for unknown indication - n/a -), (ACE)TYSALIC ACID (C - Product used for unknown indication - n/a - [n/a] - 81mg - n/a/g), (AM)LODIPINE, (AM)LODIPINE BESILATE, (AM)LODIPINE MALEATE, (AM)LODIPINE MESILATE (C - Product used for unknown indication - n/a -), (L)ONDRINE (C - Product used for unknown indication - n/a -), (HYDRO)CHLOROTHIAZIDE (C - Product used for unknown indication - n/a -), (MET)FORMIN, (MET)FORMIN HYDROCHLORIDE, (MET)FORMIN HYDROCHLORIDE BPH (C - Product used for unknown indication - n/a -), (ROSU)VASTATIN, (ROSU)VASTATIN CALCIUM (C - Product used for unknown indication - n/a -), (VAL)SARTAN (C - Product used for unknown indication - n/a -)	ICSR	
EU-EC-100073078	17/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	COVID-19 (2d - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100073542	17/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	APIXIBAN [APIXIBAN] (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), BUMETANIDE [BUMETANIDE] (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), INSULIN LISPRO [INSULIN LISPRO] (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), (ATOR)VASTATIN (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), (D)IGOXIN (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), (FL)UTICASONE PROPIONATE, (S)ALMETEROL, (X)NAFOATE (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), (L)OPERAMIDE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), (L)OSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), (M)RTAZAPINE (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), (P)ANTOPRAZOLE SODIUM (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), (P)AROXETINE MESILATE (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), (P)OTASSIUM, (P)OTASSIUM CHLORIDE, (P)OTASSIUM GLYCEROPHOSPHATE, (P)OTASSIUM HYDROGEN CARBONATE, (P)OTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), (F)AFAMIDS MEGLUMINE (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), (VITAMINS) NOS (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), CELCEPT [CYCLOPHENOLATE MOFETIL] (C - n/a - n/a -), TOUJEO [INSULIN GLARGINE] (C - n/a - n/a -), (AM)LODIPINE, (AM)LODIPINE BESILATE, (AM)LODIPINE MALEATE, (AM)LODIPINE MESILATE (C - n/a - n/a -), (ATOR)VASTATIN, (ATOR)VASTATIN CALCIUM (C - n/a - n/a -), (C)ETIRIZINE, (HYDRO)MELLOXEN (C - n/a - n/a -), (D)ICLOSPORIN (C - n/a - n/a -), (D)OLECALCIFEROL (C - n/a - n/a -), (F)ERROUS SULFATE (C - n/a - n/a -), (P)RENSONE (C - n/a - n/a -), (V)ORICONAZOLE [(V)ORICONAZOLE] (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - n/a/g), (AT)OVAQUONE (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - n/a/g)	ICSR	
EU-EC-100073599	17/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	CELCEPT [CYCLOPHENOLATE MOFETIL] (C - n/a - n/a -), TOUJEO [INSULIN GLARGINE] (C - n/a - n/a -), (AM)LODIPINE, (AM)LODIPINE BESILATE, (AM)LODIPINE MALEATE, (AM)LODIPINE MESILATE (C - n/a - n/a -), (ATOR)VASTATIN, (ATOR)VASTATIN CALCIUM (C - n/a - n/a -), (C)ETIRIZINE, (HYDRO)MELLOXEN (C - n/a - n/a -), (D)ICLOSPORIN (C - n/a - n/a -), (D)OLECALCIFEROL (C - n/a - n/a -), (F)ERROUS SULFATE (C - n/a - n/a -), (P)RENSONE (C - n/a - n/a -), (V)ORICONAZOLE [(V)ORICONAZOLE] (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - n/a/g), (AT)OVAQUONE (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - n/a/g)	ICSR	
EU-EC-100071114	17/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Acute respiratory failure (1d - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (1d - Fatal - Results in Death), Cardio-respiratory arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (1d - Fatal - Results in Death), Chest pain (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Pain (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100069536	16/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (5d - Unknown - Life Threatening), Chills (5d - Unknown - Life Threatening), Death (5d - Fatal - Results in Death, Other Medically Important Condition), Headache (5d - Unknown - Life Threatening), Pain (5d - Unknown - Life Threatening), Pyrexia (5d - Unknown - Life Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a/g), (AM)LODIPINE, (AM)LODIPINE BESILATE, (AM)LODIPINE MALEATE, (AM)LODIPINE MESILATE (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a/g), (B)IOTIN (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a/g), (C)ARVEDILOL (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a/g), (D)OLECALCIFEROL (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a/g), (E)SCITALOPRAM, (E)SCITALOPRAM OXALATE (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a/g), (F)ENCARBATE, (F)ENCARBATE MICRONISED (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a/g), (L)EVOTHYRONINE, (L)EVOTHYRONINE SODIUM (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a/g), (P)ARACETAMOL (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a/g), (VITAMINS) NOS (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a/g)	ICSR	
EU-EC-100069495	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100069586	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Abdominal pain (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Pain (n/a - Not Resolved/Not Resolved -)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [1d] - 1[Df] - n/a)	Not reported	ICSR	
EU-EC-100069799	16/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Gastroenteritis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - n/a/g)	Not reported	ICSR	
EU-EC-100070049	16/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	COVID-19 (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-100070135	16/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	(ACE)TYSALIC ACID (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	ICSR	
EU-EC-1000701419	16/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Acute kidney injury (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory distress syndrome (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthma (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Metabolic encephalopathy (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	(ACE)TYSALIC ACID (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (T)ACROLIMUS [(T)ACROLIMUS, (T)ACROLIMUS MONOHYDRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (ATOR)VASTATIN (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (C)ARVEDILOL (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (C)ITALOPRAM, (C)ITALOPRAM HYDROBROMIDE, (C)ITALOPRAM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (L)ONDRINE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (E)ROCALCIFEROL (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (M)YCOPHENOLIC ACID (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (D)IYCOZONE, (P)ARACETAMOL (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (S)ODIUM HYDROGEN CARBONATE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	ICSR	
EU-EC-1000701420	16/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Pneumonia (22d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic encephalopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	(E)LIQUIS [APIXIBAN] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (H)YDRAALZINE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (INSULIN, INSULIN HUMAN) (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	ICSR	
EU-EC-1000701467	16/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-1000701750	16/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cerebral haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-1000697310	14/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (n/a - Fatal - Results in Death, Life Threatening, Disabling), Axiillary pain (n/a - Fatal - Results in Death, Life Threatening, Disabling), Bladder hypertrophy (n/a - Fatal - Results in Death, Life Threatening, Disabling), Condition aggravated (n/a - Fatal - Results in Death, Life Threatening, Disabling), Confusional state (n/a - Fatal - Results in Death, Life Threatening, Disabling), Death (n/a - Fatal - Results in Death, Life Threatening, Disabling, Other Medically Important Condition), Dizziness (n/a - Fatal - Results in Death, Life Threatening, Disabling), Herpes zoster (n/a - Fatal - Results in Death, Life Threatening, Disabling), Hypertension (n/a - Fatal - Results in Death, Life Threatening, Disabling), Injection site mass (n/a - Fatal - Results in Death, Life Threatening, Disabling), Lung disorder (n/a - Fatal - Results in Death, Life Threatening, Disabling), Lymphadenopathy (n/a - Fatal - Results in Death, Life Threatening, Disabling), Mental status changes (n/a - Fatal - Results in Death, Life Threatening, Disabling), Oedema (n/a - Fatal - Results in Death, Life Threatening, Disabling), Pain in extremity (n/a - Fatal - Results in Death, Life Threatening, Disabling), Pulmonary artery dilation (n/a - Fatal - Results in Death, Life Threatening, Disabling, Other Medically Important Condition), Pulmonary hypertension (n/a - Fatal - Results in Death, Life Threatening, Disabling, Other Medically Important Condition), Pulmonary mass (n/a - Fatal - Results in Death, Life Threatening, Disabling), Reperitoneal lymphadenopathy (n/a - Fatal - Results in Death, Life Threatening, Disabling), Splenic lesion (n/a - Fatal - Results in Death, Life Threatening, Disabling), Tenderness (n/a - Fatal - Results in Death, Life Threatening, Disabling), Urinary tract infection (n/a - Fatal - Results in Death, Life Threatening, Disabling)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	(C)ELECOXIB [(C)ELECOXIB] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (K)EPPRA [(L)EVETTERETAM] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (T)ESTOSTERONE [(T)ESTOSTERONE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (X)ARELTO [(R)IVARABAN] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (C)ARVEDILOL (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (D)ICLOFENAC, (D)ICLOFENAC POTASSIUM, (D)ICLOFENAC SODIUM (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (H)YDROCHLOROTHIAZIDE, (T)RAMTERENE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (L)EVOTHYRONINE, (L)EVOTHYRONINE SODIUM (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (D)LODATEROL, (D)LODATEROL HYDROCHLORIDE, (T)IROPILUM (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	Not reported	ICSR
EU-EC-1000697311	14/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Haemorrhagic stroke (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown -), Zoster (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	ICSR	
EU-EC-1000697320	14/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Zoster (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiorespiratory (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (14 - Fatal - Results in Death), Hypoxia (14 - Fatal - Results in Death, Other Medically Important Condition), Lung opacity (14 - Fatal - Results in Death), Oedema (14 - Fatal - Results in Death), Pleural effusion (14 - Fatal - Results in Death), Pneumonia (14 - Fatal - Results in Death, Other Medically Important Condition), Pulmonary congestion (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	(E)LIQUIS [APIXIBAN] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (B)UMETANIDE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (FL)UTICASONE PROPIONATE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (GL)YCERYL TRINIRATE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (L)EVOTHYRONINE SODIUM (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (M)ACROGOL, (S)350 (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (M)OMETASONE FURDATE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (P)ARACETAMOL (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), (P)OTASSIUM, (P)OTASSIUM CHLORIDE, (P)OTASSIUM GLYCEROPHOSPHATE, (P)OTASSIUM HYDROGEN CARBONATE, (P)OTASS		

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Purpose	Literature Reference	Patient Age Group	Patient Sex (as per reporter)	Patient Sex	Patient Race	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Injured Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
										Death (14 - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [DOLICALFEROL] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [SABAFENTIN] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [INSULIN ASPARTIC] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [MYCOPHENOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [DXYCODONE, DXYCODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [SODIUM HYDROGEN CARBONATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown])	CSR
EU-EC-1000967596	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000967638	13/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (24 - Unknown -), Pyrexia (24 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000967687	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebrovascular accident (14 - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Facial asymmetry (14 - Unknown -), Facial spasms (14 - Unknown -), Hypertension (14 - Recovered/Resolved -), Somnolence (14 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000967762	13/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cardiac arrest (14 - Fatal - Results in Death), Death (04 - Fatal - Results in Death), Mebesic (14 - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000967842	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebrovascular accident (74 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000967870	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000967966	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	COVID-19 (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968055	13/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac arrest (14 - Fatal - Results in Death), Circulatory collapse (14 - Fatal - Results in Death), Death (04 - Fatal - Results in Death), Loss of consciousness (04 - Fatal - Results in Death), Mebesic (04 - Fatal - Results in Death), Seizure (04 - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR
EU-EC-1000968305	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (24 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968478	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (14 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (14 - Unknown -), Dyspnoea (14 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Myalgia (14 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (14 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Taste disorder (14 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968480	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	ARNEP [BARBEPEPTIN ALFA] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID, BIPYRIN, CALCIUM PANTOTHENATE, CYTOSINE, FOLIC ACID, NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, ZINC CITRATE, COBALAMIN, VITAMIN B12] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CALAMINE, ZINC OXIDE, CALAMINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DIMETICONE, ZINC OXIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DOCUSATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MENTHOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL SUCRINATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NEMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PARAFRIN WHITE SCF7] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ZINC OXIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000968565	13/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Agronosis (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cyanosis (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung opacity (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oedema (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pleur (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sputum increased (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CYANOCOBALAMIN, VITAMIN B12] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DIONEPEZIL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FERROUS SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [MAGNESIUM OXIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NEMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PRACOSINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ROBUSTINATIN, ROBUSTINATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ANJIVA [STAGLUPITIN, STAGLUPITIN PHOSPHATE MONOHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FLUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [DIPOTASSIUM CLORAZEPATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [EBASTINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [SULCLAZIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a])	CSR	
EU-EC-1000968231	12/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (14 - Fatal - Results in Death), Cardiovascular disorder (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Injection site discomfort (14 - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ANJIVA [STAGLUPITIN, STAGLUPITIN PHOSPHATE MONOHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FLUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [DIPOTASSIUM CLORAZEPATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [EBASTINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [SULCLAZIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a])	CSR
EU-EC-1000967025	12/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (04 - Fatal - Results in Death, Other Medically Important Condition)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000967353	12/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (14 - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (14 - Unknown -), Mebesic (14 - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968584	11/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (14 - Unknown -), Pyrexia (14 - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968560	11/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968589	11/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Not Specified	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968506	10/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Aortic stenosis (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968474	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (14 - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1(D) - Patient])	Not reported	CSR
EU-EC-1000968276	09/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	PROLIA [DENOSUMAB] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ACEFOLYSALICILIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ESICLAPRINAM, ESICLAPRINAM OXALATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LORATADINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOBARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [RETINOL, THIAMINE HYDROCHLORIDE, ASCORBIC ACID, EROCALCIFEROL, NODOTNAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE, RETINOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TOPIRAMATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000968279	09/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Atrialgia (14 - Fatal - Results in Death), Chills (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Fatigue (14 - Fatal - Results in Death), Headache (14 - Fatal - Results in Death), Hypertension (14 - Fatal - Results in Death), Injection site haematoma (14 - Fatal - Results in Death), Injection site inflammation (14 - Fatal - Results in Death), Injection site pain (14 - Fatal - Results in Death), Injection site warmth (14 - Fatal - Results in Death), Mebesic (14 - Fatal - Results in Death), Myalgia (14 - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - n/a])	Not reported	CSR
EU-EC-1000968284	09/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Headache (14 - Fatal - Results in Death), Acute kidney injury (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968290	09/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (14 - Fatal - Results in Death), Loss of consciousness (14 - Fatal - Results in Death, Other Medically Important Condition), Mebesic (14 - Fatal - Results in Death), Pneumonia (14 - Fatal - Results in Death, Other Medically Important Condition), Pulmonary haemorrhage (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968180	09/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (14 - Fatal - Results in Death)	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1(D) - Patient])	Not reported	CSR
EU-EC-1000968240	07/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chest discomfort (14 - Unknown -), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Vomiting (14 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968144	06/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Abdominal discomfort (14 - Unknown - Caused/Prolonged Hospitalisation), Asthma (14 - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (14 - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (14 - Unknown - Caused/Prolonged Hospitalisation), Memory impairment (14 - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (14 - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968208	06/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968240	06/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (104 - Fatal - Results in Death), Dyspnoea (104 - Fatal - Results in Death), Pyrexia (104 - Fatal - Results in Death), Vaccination complication (104 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968277	06/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chest discomfort (174 - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Discomfort (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	[LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 1(DP) - Unknown]), [METFORMIN HYDROCHLORIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - 1(DP) - Unknown])	CSR
EU-EC-1000968278	06/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968293	06/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cama (14 - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dizziness (14 - Unknown -), Headache (14 - Unknown -), Loss of consciousness (14 - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968294	06/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968306	06/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Altered state of consciousness (30min - Fatal - Results in Death, Other Medically Important Condition), Cold sweat (30min - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (30min - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968286	06/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000968287	06/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D		

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purpose	Literature Reference	Patient Age Group	Patient Sex (as per reporter)	Patient Sex	Patient Chn Report	Reaction List (Duration / Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Chn - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Chn - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
										Pyrexia (n/a - Unknown -), Respiratory arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Unknown -)				
EU-EC-1009595162	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Cardiac arrest (3d - Fatal - Results in Death), Death (3d - Fatal - Results in Death), Nausea (3d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009596820	05/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Atrioventricular block complete (n/a - Fatal - Results in Death), Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - Immunisation - Not applicable - [n/a - 5mL - Intramuscular])	Not reported	ICSR	
EU-EC-1009598885	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute kidney injury (13d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (13d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009599774	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Brain stem haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	VERAPAMIL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR	
EU-EC-1009601258	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Cerebrovascular accident (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009601602	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (2d - Fatal - Results in Death), Respiratory arrest (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 5mL - Intramuscular])	Not reported	ICSR	
EU-EC-1009601767	05/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown)	Not reported	ICSR	
EU-EC-1009602942	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Seizure (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	BUPROPION HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 150mg - Unknown]), HYDROXYCHLOROQUINE SULFATE (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown]), VIVENAFAXINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 150mg - Unknown])	ICSR	
EU-EC-1009605148	05/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death), COVID-19 pneumonia (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Encephalopathy (n/a - Fatal - Results in Death), Gastrointestinal disorder (n/a - Fatal - Results in Death), Hemodynamic instability (n/a - Fatal - Results in Death), Liver injury (n/a - Fatal - Results in Death), Shock (n/a - Fatal - Results in Death), Supraventricular tachycardia (n/a - Fatal - Results in Death), Tachycardia (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009598708	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR	
EU-EC-1009592427	04/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal distension (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Abdominal pain (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Anal incontinence (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Gastrointestinal injury (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Intensive care (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Refusal of treatment by patient (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination complication (33d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown)	Not reported	ICSR	
EU-EC-1009593773	04/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	DIPYRIDAMOLE, ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), ROBUVASATATIN, ROBUVASATATIN CALCIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Oral])	ICSR	
EU-EC-1009593828	04/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute kidney injury (9d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (9d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (9d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (9d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	FLAVIX (CLOROPYRIFEROL, CLOROPYRIFEROL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), AMLODIPINE, AMLODIPINE BESILATE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), AZELASTINE, AZELASTINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), CLONIDINE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), DOLCHICONE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), DICLOFENAC POTASSIUM (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), FLUTICASONONE PROPIONATE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), FUROSEMIDE, FUROSEMIDE SODIUM (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), HYDROCODONE BITARTRATE, PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), LIDOCANE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), MELOXICAM (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), DIMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), PRIMIDONE, PRIMIDONE (PH, EUR) (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown), ISMIVASTATIN (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown)	Not reported	ICSR
EU-EC-1009593923	03/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009597279	03/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - Life Threatening, Other Medically Important Condition), Chest pain (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CIVANCOBOLAMIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PREDNISONE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ROBUVASATATIN, ROBUVASATATIN CALCIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR	
EU-EC-1009594981	03/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Male	No	Adrenalitis (n/a - Unknown - Other Medically Important Condition), Back pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	LEVETIRACETAM (C - n/a - Unknown - [n/a - 500mg - n/a]), THIETHAZEPINE MALEATE (C - n/a - Unknown - [n/a - 6.5mg - n/a])	ICSR	
EU-EC-1009594237	03/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - Immunisation - n/a - [n/a - n/a])	PHENPROLOMON (C - n/a - n/a - n/a)	ICSR	
EU-EC-1009597578	03/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Cerebral haemorrhage (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009598629	02/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Confusional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ATELEOL, ATELEOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DOXYCYCLINE, DOXYCYCLINE HYDRATE, DOXYCYCLINE MONOHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FAMOTIDINE, FAMOTIDINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FUROSEMIDE, FUROSEMIDE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LOGARTAN, LOGARTAN POTASSIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ROBUVASATATIN, ROBUVASATATIN CALCIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), VITAMINS (NOS) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-1009598727	02/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyslipidemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown)	Not reported	ICSR	
EU-EC-1009596290	02/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Intracranial aneurysm (5d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009596283	02/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Male	No	Amyloma (1d - Fatal - Results in Death, Other Medically Important Condition), Chills (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Pain (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown)	Not reported	ICSR	
EU-EC-1009596337	02/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Agitation (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Blood glucose increased (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dysarthria (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Feeling of body temperature change (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hallucination (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hirsch (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Insomnia (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	OREDIA (ABTACEPT) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ATELEOL, ATELEOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CIVANCOBOLAMIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), SABAFENTIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), INSULIN HUMAN ZINC SUSPENSION (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), MELOXICAM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), METHOCARBAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DIMEPRAZOLE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DOXYBUTYNYN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DOXYCICLINE HYDROCHLORIDE, PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PREDNISONE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), SULFASALAZINE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-1009596468	02/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (18d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (18d - Fatal - Results in Death), Pain (18d - Fatal - Results in Death), Pain in extremity (18d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular - More in ICSR)	Not reported	ICSR	
EU-EC-1009596332	02/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009598147	02/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Cerebrovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009596282	31/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Female	No	Thrombosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009594429	30/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - 81mg - Unknown]), DOLICALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FLUOXETINE, FLUOXETINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), LAMOTRIGINE (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), LOGARTAN POTASSIUM (C - Product used for unknown indication - n/a - [n/a - 50mg - Unknown]), TAMBULOSIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 4mg - Unknown]), DOXYBUTYNYN (DOXYBUTYNYN, DOXYBUTYNYN HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10095945478	30/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Melaena (n/a - Fatal - Results in Death)	SPRIEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), BIPERIDEN HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), COLECALCIFEROL (C - n/a - n/a - [n/a - n/a - n/a]), DICLOFENAC SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral - More in ICSR]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]), METFORMIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 500mg - Unknown])	ICSR	
EU-EC-1009596522	30/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Multifocal retinal detachment (n/a - Fatal - Results in Death) Cerebrovascular accident (2d - Fatal - Results in Death), Cerebrovascular accident (2d - Fatal - Results in Death, Other Medically Important Condition), Death (2d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009591194	30/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1009596227	30/07/2021	Spont												

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country or Regulatory Purpose	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Status	Patent Chg. Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Subject/Modifying Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-100953076	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Autoimmune haemolytic anaemia (974 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (974 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (974 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (974 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intensive care (974 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Splenectomy (974 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (974 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-100953254	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Death (974 - Fatal - Results in Death, Other Medically Important Condition), Erythema (35 - Fatal - Results in Death), Nodules (35 - Fatal - Results in Death), Peripetral swelling (35 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1009537818	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Abdominal pain upper (566 - Fatal - Results in Death, Life Threatening, Disabling), Back pain (566 - Fatal - Results in Death, Life Threatening, Disabling), Blindness (566 - Fatal - Results in Death, Life Threatening, Disabling, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Life Threatening, Disabling, Other Medically Important Condition), Nausea (566 - Fatal - Results in Death, Life Threatening, Disabling, Other Medically Important Condition), Anorexia (724 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Anti-neurophil cytoplasmic antibody positive vasculitis (724 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood disorder (724 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (724 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hypoglycaemia (724 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (724 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown])	ICSR
EU-EC-100951206	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Pharmacoallergy (566 - Fatal - Results in Death, Life Threatening, Disabling, Other Medically Important Condition), Anorexia (724 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Anti-neurophil cytoplasmic antibody positive vasculitis (724 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (724 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hypoglycaemia (724 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Renal failure (724 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Unknown - More in ICSR)	[CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE, CIPROFLOXACIN LACTATE] (C - Product used for unknown indication - n/a - [974 - n/a - n/a])	ICSR
EU-EC-1009504178	23/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Abdominal pain upper (974 - Unknown -), Cardiac disorder (974 - Unknown -), Chest discomfort (974 - Unknown -), Chest pain (974 - Unknown -), Death (974 - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (974 - Unknown -), Dyspnoea (974 - Unknown -), Feeding disorder (974 - Unknown -), General physical health deterioration (974 - Unknown -), Hives (974 - Unknown -), Hives (974 - Unknown - Caused/Prolonged Hospitalisation), Insomnia (974 - Unknown -), Lung disorder (974 - Unknown -), Myocardial infarction (974 - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (974 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (974 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	BROMIDE [AMMONIUM BROMIDE, POTASSIUM BROMIDE, SODIUM BROMIDE] (C - Product used for unknown indication - Unknown - [974 - 1DP] - Unknown), [RUPINORPHINE, [RUPINORPHINE] (C - Pancreatic chronic - Unknown - [974 - 16mg - Unknown]), [PANTOPRAZOLE, [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Pancreatic chronic - Unknown - [974 - 80mg - Unknown]), [DIAZEPAM] (C - Product used for unknown indication - Unknown - [974 - 1DP] - Unknown), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Depressed mood - Unknown - [974 - 60mg - Unknown]), [LOSARTAN POTASSIUM] (C - Hypertension - Unknown - [974 - 50mg - Unknown]), [ONDANSETRON] (C - Pancreatic chronic - Unknown - [974 - 16mg - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Pancreatic chronic - Unknown - [974 - 1DP] - Unknown), [TIOTROPUM, TIOTROPUM BROMIDE, TIOTROPUM BROMIDE MONOHYDRATE] (C - Product used for unknown indication - Unknown - [974 - 1DP] - Unknown)	ICSR
EU-EC-1009518312	23/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	No	Death (974 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1009518271	23/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (974 - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - Immunisation - n/a - [974 - n/a - n/a])	Not reported	ICSR
EU-EC-100951987	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Cerebrovascular accident (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	[ALLOPURINOL] (C - Product used for unknown indication - n/a - [974 - 100mg - Unknown]), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [974 - 12.5mg - Unknown]), [BIMASTATIN] (C - Product used for unknown indication - n/a - [974 - 5mg - Unknown]), [NEPRA 20 AND ELECTROLYTE TABLETS] (C - n/a - n/a - [974 - 2DP] - Oral), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [974 - 1DP] - Oral), [METAZOLE, METAZOLE SODIUM, METAZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [974 - 3DP] - Oral), [PROPRANOLOL HYDROCHLORIDE] (C - n/a - n/a - [974 - 2DP] - Oral), [GABAPENTIN] (C - Product used for unknown indication - n/a - [974 - 800mg - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [974 - n/a - n/a])	ICSR
EU-EC-100952374	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Male	No	No	Death (974 - Fatal - Results in Death), Pulmonary embolism (974 - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - Immunisation - n/a - [974 - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100952369	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Cardiac disorder (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Heart rate irregular (14 - Fatal - Results in Death), Memory impairment (14 - Fatal - Results in Death), Sleep apnoea syndrome (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Unknown)	[LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [974 - n/a - n/a])	ICSR
EU-EC-100948327	26/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	COVID-19 (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cardiomyopathy (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (974 - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (14 - Unknown -), Haemophilus infection (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mental status changes (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (974 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (974 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Septic shock (14 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccine breakthrough infection (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular tachycardia (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100948796	23/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	No	Death (974 - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [14 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100941987	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (974 - Unknown - Caused/Prolonged Hospitalisation), General physical health deterioration (974 - Unknown - Caused/Prolonged Hospitalisation), Nausea (974 - Unknown - Caused/Prolonged Hospitalisation), Pneumonitis (974 - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (974 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	[INSULIN, INSULIN HUMAN] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown])	ICSR
EU-EC-1009448324	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (974 - Fatal - Results in Death, Other Medically Important Condition), Resuscitation (974 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1009448549	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Herpes zoster (654 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1009448697	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Thrombosis (974 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1009448724	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Asthma (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Blindness unilateral (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cutaneous vasculitis (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyschromatopsia (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), General physical health deterioration (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Photopsia (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vasculitis (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vision blurred (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Visual impairment (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Vitreous floaters (974 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular - More in ICSR)	[ASCORBIC ACID], [CALCIUM GLUBONATE], [CALCIUM CARBONATE], [CALCIUM GLUBONATE], [CALCIUM CARBONATE], [COLECALCIFEROL], [CALCIUM] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [BIOTIN] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [DOLECALCIFEROL] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [LEVOTHYRONE SODIUM] (C - Product used for unknown indication - n/a - [974 - 25ug - Unknown]), [PRENISOONE] (C - Product used for unknown indication - n/a - [974 - 10mg - n/a])	ICSR
EU-EC-1009448463	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	[ASCORBIC ACID], [CALCIUM GLUBONATE], [CALCIUM CARBONATE], [CALCIUM GLUBONATE], [CALCIUM CARBONATE], [COLECALCIFEROL], [CALCIUM] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [DOLECALCIFEROL] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [DIMEPRIZOLE, DIMEPRIZOLE MAGNESIUM] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown])	ICSR
EU-EC-1009449518	23/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Adverse reaction (974 - Unknown -), Back pain (974 - Unknown -), Bedridden (974 - Unknown -), Chest pain (974 - Unknown -), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Eye movement disorder (974 - Unknown -), Hypokalaemia (974 - Unknown -), Inappropriate schedule of product administration (974 - Recovered/Resolved -), Malaise (974 - Unknown -), Nack pain (974 - Unknown -), Soreness (974 - Unknown -), Swelling (974 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1009449589	23/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Agonist (04 - Fatal - Results in Death, Other Medically Important Condition), Cardiac arrest (04 - Fatal - Results in Death, Other Medically Important Condition), Cyanosis (04 - Fatal - Results in Death, Other Medically Important Condition), Death (04 - Fatal - Results in Death, Other Medically Important Condition), Fatigue (974 - Fatal - Results in Death, Other Medically Important Condition), Myalgia (974 - Fatal - Results in Death, Other Medically Important Condition), Mydriasis (04 - Fatal - Results in Death, Other Medically Important Condition), Pulmonary embolism (04 - Fatal - Results in Death, Other Medically Important Condition)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - n/a - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1009449605	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	COVID-19 (974 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (180 - Fatal - Results in Death, Other Medically Important Condition), Vaccine breakthrough infection (974 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1009449656	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Cardiac arrest (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Intercardiac thrombus (14 - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Myocardial infarction (14 - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [ALPHA GALACTOSIDASE A] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [DIMEPRIZOLE] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown])	ICSR
EU-EC-1009449342	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Abdominal pain upper (474 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cognitive disorder (474 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (474 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dehydration (474 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (474 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Haematuria (474 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Skin exfoliation (474 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Headache - Unknown - [974 - 1DP] - Unknown), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Dyspnoea - Unknown - [974 - 1DP] - Unknown), [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a - [974 - 1DP] - Unknown)	ICSR
EU-EC-1009449424	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Partial seizures (974 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (974 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1009449425	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	COVID-19 (14 - Unknown - Caused/Prolonged Hospitalisation), Cervical vertebral fracture (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Fall (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1009449483	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1009449490	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Cardioversion (974 - Fatal - Results in Death), Death (974 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (974 - Fatal - Results in Death), Respiratory tract congestion (974 - Fatal - Results in Death), Resuscitation (974 - Fatal - Results in Death), Unresponsive to stimuli (974 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular)	[ANORO] [UMECILINIUM BROMIDE, VILANTEROL] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [DARVENZOL] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [DELTAZEM, DELTAZEM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [FLUTICASON, FLUTICASON PROPIONATE] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [LEVOTHYRONE, LEVOTHYRONE SODIUM] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [MIRTAZAPINE] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [RSBUVATATIN, RSBUVATATIN CALCIUM] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [974 - n/a - Unknown])	ICSR
EU-EC-1009449420	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Acute respiratory failure (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardio-respiratory arrest (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chronic eosinophilic leukæmia (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eosinophilia (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Large intestinal ulcer (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle spasms (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myalgia (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oesophageal ulcer (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Rash (364 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [974 - 1DP] - Intramuscular - More in ICSR)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [9	

EU Local Number	EY Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex (as self-reported)	Patient Sex	Patient Race	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspecting/Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000445795	23/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Thrombosis (36) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition) Condition aggravated (16) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Death (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Weight decreased (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	ACEZOLAMIDE (C - Cardiac failure congestive - n/a - [19] - n/a - Oral), SALBUTAMOL SULFATE (C - Product used for unknown indication - n/a - [19] - n/a - Inj)	CSR
EU-EC-1000441804	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac arrest (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (19) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling abnormal (19) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (19) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (19) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Unknown)	Not reported	CSR
EU-EC-1000442688	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Renal disorder (19) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Death (14) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Unknown)	JANUVA [SITAGLIPITIN, SITAGLIPITIN PHOSPHATE, SITAGLIPITIN PHOSPHATE MONOHYDRATE] (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), LANTUS [INSULIN GLARGINE] (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), XARELTO [RIVAROXABAN] (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), ALUMINUM HYDROXIDE GEL, MAGNESIUM HYDROXIDE, ALUMINUM OXIDE, HYDRATED, MAGNESIUM HYDROXIDE, ALUMINUM OXIDE, MAGNESIUM HYDROXIDE, MAGNESIUM HYDROXIDE BP, SIBIRED, ALUMINUM HYDROXIDE BP, MAGNESIUM HYDROXIDE, ALGEBLATE, MAGNESIUM HYDROXIDE, ALUMINUM HYDROXIDE, MAGNESIUM HYDROXIDE, ALUMINUM OXIDE COLLOIDAL (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), ASCORBIC ACIDS (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), CRAMBERRY (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), DICLOFENAC, DICLOFENAC DIETHYLAMINE, DICLOFENAC EPOLAMINE, DICLOFENAC POTASSIUM, DICLOFENAC RESINATE, DICLOFENAC SODIUM, DICLOFENAC SODIUM PH. EUR (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), GLYCERYL TRINERATE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), MACROGOL 3350 (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), MAGNESIUM CHLORIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), MAGNESIUM HYDROXIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), DIMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), PARACETAMOL (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), POTASSIUM CHLORIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), TORASEMIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), TRAZODONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), VACCINUM L (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), VITAMINS NOS (C - Product used for unknown indication - n/a - [19] - n/a - Unknown)	CSR
EU-EC-1000443363	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000444291	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Coronary artery disease (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepomegaly (14) - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	AMTRIPTYLINE, AMTRIPTYLINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [19] - [1DF] - Unknown), BUSPIRONE (C - Product used for unknown indication - n/a - [19] - [1DF] - Unknown), CLONAZEPAM (C - Product used for unknown indication - n/a - [19] - [1DF] - Unknown), HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - n/a - [19] - [1DF] - Unknown), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [19] - [1DF] - Unknown)	CSR
EU-EC-1000445678	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000445971	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiovascular accident (21) - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (21) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (21) - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000446000	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (21) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (21) - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000446199	21/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (19) - Fatal - Results in Death, Other Medically Important Condition), Death (19) - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (19) - Fatal - Results in Death, Other Medically Important Condition), Feeling abnormal (19) - Fatal - Results in Death, Other Medically Important Condition), Headache (19) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000446255	21/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Brain death (19) - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (14) - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Coma (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (19) - Fatal - Results in Death), Dyspnoea (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocardial infarction (19) - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory arrest (19) - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000442360	20/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (19) - Fatal - Results in Death)	SPRIVAX (S - n/a - n/a - [19] - n/a - Inj)	Not reported	CSR
EU-EC-1000442107	20/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac arrest (19) - Fatal - Results in Death), Death (19) - Fatal - Results in Death), Sudden death (19) - Fatal - Results in Death)	SPRIVAX (S - COVID-19 - Does not changed - [19] - n/a - Outpatient)	Not reported	CSR
EU-EC-1000442573	20/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	BRACOPOL, DOUBATE SODIUM, SODIUM POLYSILBATE MONOHYDRATE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), DOUGATE SODIUM (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), DOBAPENTIN (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), MACROGOL 3350 (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), PARACETAMOL (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), TRAZODONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), VENAFAXINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown)	CSR
EU-EC-1000446368	20/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthma (34 - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (14) - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (19) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (19) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hematuria (34 - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pancytopenia (34 - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	XARELTO [RIVAROXABAN] (C - Arterial fibrillation - n/a - [19] - n/a - Oral), ATORVASTATIN (C - Blood cholesterol - n/a - [19] - n/a - Oral), CARVEDILOL (C - Arterial fibrillation - n/a - [19] - n/a - Oral), CARVEDILOL (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), FERROUS SULFATE (C - Anemia - n/a - [19] - n/a - Oral), FUROSEMIDE, FUROSEMIDE SODIUM (C - Cardiac failure congestive - n/a - [19] - n/a - Oral), FUROSEMIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), PRAVASTATIN, PRAVASTATIN SODIUM (C - Product used for unknown indication - n/a - [19] - n/a - Unknown)	CSR
EU-EC-1000441464	19/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased appetite (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of consciousness (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000441668	19/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Thrombotic thrombocytopenic purpura (14) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition) Death (19) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	BACITRACIN ZINC, NEDIGAMY SULFATE, POLYMYXIN B SULFATE (C - n/a - n/a -), DIETHYLAMINE SALICYLATE (C - n/a - n/a -), HALOPERIDOL, HALOPERIDOL DECANOATE (C - n/a - n/a -), LORAZEPAM (C - n/a - n/a -), METHYL NICOTINATE (C - n/a - n/a -), MORPHINE SULFATE (C - n/a - n/a -), PARACETAMOL (C - n/a - n/a -), TROLAMINE SALICYLATE (C - n/a - n/a -)	CSR
EU-EC-1000441785	19/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (19) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000446216	19/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Acute respiratory distress syndrome (14) - Fatal - Results in Death, Other Medically Important Condition), Acute respiratory failure (14) - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (14) - Fatal - Results in Death, Other Medically Important Condition), COVID-19 pneumonia (14) - Fatal - Results in Death, Other Medically Important Condition), Death (14) - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000446563	19/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypotensive state (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (19) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [19] - [1DF] - Unknown)	Not reported	CSR
EU-EC-1000446228	19/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14) - Fatal - Results in Death, Other Medically Important Condition), Inappropriate schedule of product administration (19) - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular - More in ICSR)	KEPPRA [LEVETIRACETAM] (C - Product used for unknown indication - n/a - [19] - 750mg - n/a), CLANZAPINE [CLANZAPINE] (C - Product used for unknown indication - n/a - [19] - 10mg - n/a), SIBUXONE [BUPRENORPHINE, NALOXONE, NALOXONE HYDROCHLORIDE DIHYDRATE, BUPRENORPHINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [19] - n/a - n/a), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [19] - 81mg - n/a), AMTRIPTYLINE, AMTRIPTYLINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [19] - 50mg - n/a), ATORVASTATIN (C - Product used for unknown indication - n/a - [19] - 40mg - n/a), CHLORPHAZAMINE, CHLORPHAZAMINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [19] - 100mg - n/a), DOXEPRIN, DOXEPRIN HYDROCHLORIDE, DOXEPRIN HYDROCHLORIDE BP (C - Product used for unknown indication - n/a - [19] - 10mg - n/a), SABAFENTIN (C - Product used for unknown indication - n/a - [19] - 800mg - n/a), HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - n/a - [19] - n/a - n/a), INSULIN GLARGINE (C - Product used for unknown indication - n/a - [19] - n/a - n/a), INSULIN LISPRO (C - Product used for unknown indication - n/a - [19] - n/a - n/a), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [19] - 40mg - n/a), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP (C - Product used for unknown indication - n/a - [19] - 1000mg - n/a), LIXIANA [EDOXABAN, EDOXABAN TOSYLATE] (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), VIPCODIN [METFORMIN HYDROCHLORIDE, ALOGLIPTIN] (C - Product used for unknown indication - n/a - [19] - n/a - n/a), DOXADEXIN, DOXADEXIN MESILATE (C - Product used for unknown indication - n/a - [19] - n/a - n/a), EZETIMIBE (C - Product used for unknown indication - n/a - [19] - 10mg - Unknown), RAMPRII (C - Product used for unknown indication - n/a - [19] - n/a - Unknown)	CSR
EU-EC-1000441960	19/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (89) - Fatal - Results in Death), COVID-19 (19) - Fatal - Results in Death, Other Medically Important Condition), Death (14) - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (89) - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (89) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (89) - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Unknown)	ACEFYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), ATORVASTATIN (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), ATROPINE SULFATE Ph. EUR., DIPHENOXYLATE HYDROCHLORIDE BP, ATROPINE SULFATE, DIPHENOXYLATE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), BIRMONDINE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), DORZOLAMIDE, DORZOLAMIDE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), FUROSEMIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), LATANOPROST (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), MAGNESIUM CHLORIDE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), MYCOPHENOLIC ACID (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), DIMEPRAZOLE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), POLYVINYL ALCOHOL (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), PREDNISONE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), TACROLIMUS, TACROLIMUS MONOHYDRATE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), TIMOLOL, TIMOLOL MALEATE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), VITAMINS NOS (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - Product used for unknown indication - n/a - [19] - n/a - Unknown), INSULIN, INSULIN HUMAN (C - Product used for unknown indication - n/a - [19] - n/a - Unknown)	CSR
EU-EC-1000441214	19/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 pneumonia (13) - Fatal - Results in Death, Other Medically Important Condition), Cardiac failure (13) - Fatal - Results in Death, Other Medically Important Condition), Death (14) - Fatal - Results in Death, Other Medically Important Condition), Elevated creatinine (13) - Fatal - Results in Death, Other Medically Important Condition), Urinary tract infection (13) - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000443480	17/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14) - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (14) - Recovered/Resolved - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [19] - [1DF] - Intramuscular)	Not reported	CSR
EU-EC-1000443213	16/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac arrest (3) - Fatal - Results in Death, Other Medically Important Condition), Death (3) - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (14) - Fatal - Results in Death, Other Medically Important Condition)	SPRIVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - n/a - [19] - [1DF] - Intramuscular)	GLUCILAZIDE (C - n/a - n/a - [19] - n/a - Oral), NEBIVOLOL (C - n/a - n/a - [19] - n/a - Oral), OLMESARTAN MEDOXOMIL, ALOMDIPINE, OLMESARTAN MEDOXOMIL, AMLODIPINE BESILATE (C - n/a - n/a - [19] - n/a - Oral)	CSR

EU Local Number	EY Review Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Purpose	Literature Reference	Patient Age Group	Patient Sex (as per reporter)	Patient Sex	Patient Chirality	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
										Hypertensive heart disease (D1 - Fatal - Results in Death, Other Medically Important Condition), Pulmonary embolism (I1 - Fatal - Results in Death, Other Medically Important Condition), Respiratory arrest (D1 - Fatal - Results in Death, Other Medically Important Condition)		PARACETAMOL (C - n/a - n/a - n/a - Oral)	
EU-EC-10009362909	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (I1 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - None in ICSR])	Not reported	ICSR
EU-EC-10009363031	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Agitation (85 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Asthma (85 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Blurry vision (85 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac failure congestive (85 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (I1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (85 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hallucination (85 - Fatal - Results in Death, Other Medically Important Condition), Hepatic pain (85 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hyperventilation (85 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hives (85 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Unknown -), Pleural effusion (85 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (85 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal impairment (85 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sleep disorder (85 - Recovered/Not Recovered -), Death (I1 - Fatal - Results in Death, Other Medically Important Condition), Reactivation (I1 - Fatal - Results in Death), Unresponsive to stimuli (I1 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - None in ICSR])	Not reported	ICSR
EU-EC-1000936365	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (I1 - Fatal - Results in Death, Other Medically Important Condition), Reactivation (I1 - Fatal - Results in Death), Unresponsive to stimuli (I1 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	XARELTO (RIVAROXABAN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FLUTICASON PROPRIONATE, SALMETEROL XINAFOATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), SALBUTAMOL, SALBUTAMOL SULFATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-10009364167	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	COVID-19 (S1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (I1 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-10009364215	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	ICSR
EU-EC-10009367962	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (I1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (I1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (I1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - None in ICSR])	Not reported	ICSR
EU-EC-10009367984	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (I1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	ICSR
EU-EC-10009368480	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (I1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-10009368624	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (I1 - Fatal - Results in Death, Other Medically Important Condition), Dizziness (D1 - Not Recovered/Not Resolved -), Ooziness (D1 - Not Recovered/Not Resolved -), Pneumia (D1 - Not Recovered/Not Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	MONOCLONAL ANTIBODIES, GRANULOCYTE (C - COVID-19 - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-10009369276	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (I1 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	MELATONIN (MELATONIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ANHYDROUS LIDOCAINE HYDROCHLORIDE, EPINEPHRINE BITARTRATE, LIDOCAINE HYDROCHLORIDE, EPINEPHRINE, LIDOCAINE HYDROCHLORIDE, LIDOCAINE, LIDOCAINE HYDROCHLORIDE MONOHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CALCIUM (BALANCE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), COLICAPROFENOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DOLACICLOFENAC (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DOLACICLOFENAC POTASSIUM, DOLACICLOFENAC SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FLUTICASON PROPRIONATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), MACRODOL 3300 (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), MAGNESIUM HYDROXIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), MEMANTINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), OXCODONE, OXCODONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), TRAZODONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), VALPROATE SEMISODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), VALPROATE SEMISODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), REVALBETULUMIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LANTUS INSULIN GLARGINE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LALOPURINOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), AMOXICILLIN SODIUM, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CALCIUM CARBONATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DIFENOPEZOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FERROUS GLUCONATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), GABAPENTIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), MIRTAZAPIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DIMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PREDNISONE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), TRAMADOL, TRAMADOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), VITAMIN B12 (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ACETYLSALICYLIC ACID, ASPIRIN (C - n/a - n/a -)	ICSR
EU-EC-10009369456	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (I1 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - None in ICSR])	Not reported	ICSR
EU-EC-10009369460	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (I1 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - None in ICSR])	Not reported	ICSR
EU-EC-10009369538	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-10009369696	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Axemia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Asthma (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Meningitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tremor (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Varicella zoster virus infection (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	FLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FLURALAZINE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ISOSORBIDE MONONITRATE, ISOSORBIDE MONONITRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PRAVASTATIN, PRAVASTATIN SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TRIAMTERENE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009369700	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown -), Confusional state (n/a - Unknown -), Death (I1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Hallucination (n/a - Unknown - Other Medically Important Condition), Myxema gravis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-10009369808	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (245 - Fatal - Results in Death), Cardiac arrest (245 - Fatal - Results in Death, Other Medically Important Condition), Death (I1 - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	ICSR
EU-EC-10009369904	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Failure to thrive (245 - Fatal - Results in Death, Other Medically Important Condition) Death (I1 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-100093699128	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Gastrointestinal disorder (I1 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-100093699424	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-100093699524	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute kidney injury (45 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (44 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	ICSR
EU-EC-100093699578	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Alveolitis (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocarditis (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	CANFENDELS (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DICLOFENAC HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), SABAPENTIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), HYDROCHLOROTHIAZIDE, LISINAPRIL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), NORTRIPTYLINE, NORTRIPTYLINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DIMEPRAZOLE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-100093699583	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (I1 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000936991947	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cardiac failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), General physical health deterioration (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Renal impairment (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Thoracic aortic aneurysm (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Transient ischaemic attack (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000936992062	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COVID-19 (105 - Fatal - Results in Death), Death (I1 - Fatal - Results in Death, Other Medically Important Condition), Hypertensive heart disease (I05 - Fatal - Results in Death), Left ventricular failure (I05 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	ICSR
EU-EC-1000936992470	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	XARELTO (RIVAROXABAN) (C - Adverse event - n/a - [n/a - n/a - n/a]), ATONIVASTATIN CALCIUM (C - Adverse event - n/a - [n/a - n/a - n/a]), BENCOXATE (C - Adverse event - n/a - [n/a - n/a - n/a]), EVANCOBALAMIN, VITAMIN B12 (C - Adverse event - n/a - [n/a - n/a - n/a]), DILTIAZEM HYDROCHLORIDE (C - Adverse event - n/a - [n/a - n/a - n/a]), EUCERIN, UREA, WOOL ALCOHOLS (C - Adverse event - n/a - [n/a - n/a - n/a]), FLUTICASON PROPRIONATE (C - Adverse event - n/a - [n/a - n/a - n/a]), FUROSEMIDE, FUROSEMIDE SODIUM (C - Adverse event - n/a - [n/a - n/a - n/a]), LORAZEPAM (C - Adverse event - n/a - [n/a - n/a - n/a]), LOSARTAN POTASSIUM (C - Adverse event - n/a - [n/a - n/a - n/a]), MACRODOL 3300 (C - Adverse event - n/a - [n/a - n/a - n/a]), METFORMIN HYDROCHLORIDE (C - Adverse event - n/a - [n/a - n/a - n/a]), PARACETAMOL (C - Adverse event - n/a - [n/a - n/a - n/a]), POTASSIUM CHLORIDE (C - Adverse event - n/a - [n/a - n/a - n/a]), ROPINIROLE, ROPINIROLE HYDROCHLORIDE (C - Adverse event - n/a - [n/a - n/a - n/a]), SALBUTAMOL SULFATE (C - Adverse event - n/a - [n/a - n/a - n/a]), SALICYLIC ACID (C - Adverse event - n/a - [n/a - n/a - n/a]), TROTROPICAM, TROTROPICAM BROMIDE, TROTROPICAM BROMIDE MONOHYDRATE (C - Adverse event - n/a - [n/a - n/a - n/a]), ALLIUM SATIVUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ASCORBIC ACID, ALPHACETOPHEROL ACETATE (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), ASCORBIC ACID (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), FISH OIL (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), LUBIDECARENONE (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown])	ICSR
EU-EC-1000936992541	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cardiac failure congestive (24 - Fatal - Results in Death, Other Medically Important Condition), Chronic kidney disease (24 - Fatal - Results in Death, Other Medically Important Condition), Death (I1 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (24 - Fatal - Results in Death), Hypertension (24 - Fatal - Results in Death), Oesophageal stenosis (24 - Fatal - Results in Death, Other Medically Important Condition), Pneumonia aspiration (24 - Fatal - Results in Death, Other Medically Important Condition), Pyl (n/a - Fatal - Results in Death), Haemorrhagic urinary tract (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	ICSR
EU-EC-1000936992548	16/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthma (n/a - Fatal - Results in Death), Arrhythmia block (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death), Pyl (n/a - Fatal - Results in Death), Haemorrhagic urinary tract (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - None in ICSR])	BENZAEPRI (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), CARBIDOPA, LEVO-DOPA, LEVO-DOPA, CARBIDOPA MONOHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DILTIAZEM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), ESGICLOPRAM, ESGICLOPRAM OXALATE (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), LEVOTHYRAXINE, LEVOTHYRAXINE SODIUM (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown])	ICSR

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Chn Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Supporting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
										<p>Anal fibrillation (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>COVID-19 (n/a - Fatal - Results in Death),</p> <p>Chronic kidney disease (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Condition aggravated (n/a - Fatal - Results in Death),</p> <p>Death (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Diabetes mellitus (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Drug ineffective (n/a - Fatal - Results in Death),</p> <p>Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Respiratory disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Urinary tract infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>COVID-19 (2d - Unknown - Caused/Prolonged Hospitalisation),</p> <p>COVID-19 pneumonia (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Death (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Drug ineffective (1d - Unknown -),</p> <p>Dyspnoea (2d - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Headache (2d - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Nausea (2d - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Yawning (2d - Unknown - Caused/Prolonged Hospitalisation)</p>				
EU-EC-1000935366	13/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	<p>Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Respiratory disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Urinary tract infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000935433	13/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	<p>COVID-19 (2d - Unknown - Caused/Prolonged Hospitalisation),</p> <p>COVID-19 pneumonia (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Death (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Drug ineffective (1d - Unknown -),</p> <p>Dyspnoea (2d - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Headache (2d - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Nausea (2d - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Yawning (2d - Unknown - Caused/Prolonged Hospitalisation)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000935420	13/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	85-89 Years	Not Specified	Female	No	<p>Death (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Dyspnoea (8d - Fatal - Results in Death),</p> <p>Mobility decreased (8d - Fatal - Results in Death),</p> <p>Postprandial sweating (8d - Fatal - Results in Death),</p> <p>Posture abnormal (8d - Fatal - Results in Death)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000935698	13/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-84 Years	Not Specified	Male	No	<p>Death (1d - Fatal - Results in Death, Other Medically Important Condition)</p>	<p>SPINEVA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])</p> <p>ADITYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - 100mg - Oral]),</p> <p>AMODIAZONE, AMODIAZONE HYDROCHLORIDE (C - Product used for unknown indication - Not applicable - [n/a - 200mg - Oral]),</p> <p>PERINDOPRIL, PERINDOPRIL TERZ BUTYLAMINE (C - Product used for unknown indication - n/a - [n/a - 4mg - Oral])</p>	Not reported	ICSR	
EU-EC-1000935628	13/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	<p>Acute myocardial infarction (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Areflexia (1d - Fatal - Results in Death),</p> <p>Cardiac arrest (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Chest pain (1d - Fatal - Results in Death),</p> <p>Death (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Dyspnoea (1d - Fatal - Results in Death),</p> <p>General physical health deterioration (1d - Fatal - Results in Death),</p> <p>Myocardia (1d - Fatal - Results in Death),</p> <p>Pulmonary embolism (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Pulse absent (1d - Fatal - Results in Death),</p> <p>Pulseless electrical activity (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Pupil fixed (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Respiratory arrest (1d - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000935634	13/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	85-89 Years	Not Specified	Male	No	<p>Death (1d - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - More in ICSR])	Not reported	ICSR	
EU-EC-1000935654	13/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Lymphadenopathy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Lymphoproliferative disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Septic (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Death (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Rheumatoid arthritis (n/a - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	<p>CELECOXIB (CELECOXIB) (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]),</p> <p>ALPRAZOLAM (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]),</p> <p>[CHLORTALIDONE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]),</p> <p>[DILTIAZEM HYDROCHLORIDE, CTALOPRAM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - Unknown])</p>	Not reported	ICSR
EU-EC-1000937023	13/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Septic (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Death (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Rheumatoid arthritis (n/a - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	HUMIRA (ADALIMUMAB) (C - Rheumatoid arthritis - n/a - [n/a - 1(DP) - Unknown])	Not reported	ICSR
EU-EC-1000937157	13/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	85-89 Years	Not Specified	Male	No	<p>Death (n/a - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	ADITYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), <p>[METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])</p>	Not reported	ICSR
EU-EC-1000934480	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Atherosclerosis coronary artery (75d - Fatal - Results in Death),</p> <p>Athetosis (75d - Fatal - Results in Death),</p> <p>Bone pain (75d - Fatal - Results in Death),</p> <p>Chest pain (75d - Fatal - Results in Death),</p> <p>Condition aggravated (75d - Fatal - Results in Death),</p> <p>Cough (75d - Fatal - Results in Death),</p> <p>Death (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Fatigue (75d - Fatal - Results in Death),</p> <p>Fingers abnormal (75d - Fatal - Results in Death),</p> <p>Hypopnea (75d - Fatal - Results in Death),</p> <p>Lethargy (75d - Fatal - Results in Death),</p> <p>Myocardial infarction (75d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Myocardial ischaemia (75d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Pain (75d - Fatal - Results in Death),</p> <p>Reactivation (75d - Fatal - Results in Death),</p> <p>Rhinorrhoea (75d - Fatal - Results in Death),</p> <p>Seizure (75d - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - More in ICSR])	Not reported	ICSR	
EU-EC-1000934919	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	<p>Death (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Dyspepsia (n/a - Fatal - Results in Death),</p> <p>Diarrhoea (n/a - Fatal - Results in Death),</p> <p>Urinary tract infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Urinary tract infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000935606	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-84 Years	Not Specified	Male	No	<p>Respiratory disorder (n/a - Fatal - Results in Death),</p> <p>Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Urinary tract infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - More in ICSR])	Not reported	ICSR	
EU-EC-1000935750	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-84 Years	Not Specified	Female	No	<p>COVID-19 (n/a - Fatal - Results in Death),</p> <p>Condition aggravated (n/a - Fatal - Results in Death),</p> <p>Death (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Diabetes mellitus (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Hypertension (n/a - Fatal - Results in Death),</p> <p>Respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	ICSR	
EU-EC-1000935690	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-84 Years	Not Specified	Female	No	<p>COVID-19 pneumonia (14d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Chronic obstructive pulmonary disease (14d - Fatal - Results in Death),</p> <p>Condition aggravated (14d - Fatal - Results in Death),</p> <p>Death (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Drug ineffective (n/a - Unknown -),</p> <p>COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>COVID-19 pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Decreased appetite (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Depressed level of consciousness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Diarrhoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Hypoglycaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Ischaemic stroke (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	ICSR	
EU-EC-1000935676	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-84 Years	Not Specified	Male	No	<p>COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>COVID-19 pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Depressed appetite (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Depressed level of consciousness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Diarrhoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Hypoglycaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Ischaemic stroke (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	<p>AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>BISACODYL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>[CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>[COLECALCIFEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>FERROUS SULFATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>FERRUS SULFATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>[GUARINESIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>HYDRAZONE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>LACTULOSE, LACTULOSE ACIDIPOLIS (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>LIDOCANE, LIDOCANE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>[LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>[PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>[SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>[PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 650mg - n/a]),</p> <p>[SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - 2(DP) - Nasal])</p>	Not reported	ICSR
EU-EC-1000935679	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Confusional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Fatigue abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Syncope (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	<p>ELIQUIS (APIXIBAN) (C - Embolism venous - n/a - [n/a - n/a - Unknown]),</p> <p>PREGABALIN (PREGABALIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>[CLONAZEPAM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>[HYDROCODONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>[INSULIN, INSULIN HUMAN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>[LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>[METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>[TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>[VMPAT, LACOSAMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>[VALPROATE SEMISODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])</p>	Not reported	ICSR
EU-EC-1000937473	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	<p>Death (1d - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - More in ICSR])	Not reported	ICSR	
EU-EC-1000937704	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-84 Years	Not Specified	Male	No	<p>Death (n/a - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - More in ICSR])	Not reported	ICSR	
EU-EC-1000938403	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-84 Years	Not Specified	Male	No	<p>Coronary artery disease (10d - Fatal - Results in Death),</p> <p>Death (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Diabetic neuropathy (10d - Fatal - Results in Death),</p> <p>End stage renal disease (10d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Hypertension (10d - Fatal - Results in Death),</p> <p>Type 2 diabetes mellitus (10d - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	ICSR	
EU-EC-1000939960	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-84 Years	Not Specified	Male	No	<p>Death (1d - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	ELIQUIS (APIXIBAN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-1000939969	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Death (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Dyspnoea (n/a - Fatal - Results in Death),</p> <p>Vaccination site pain (n/a - Fatal - Results in Death)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - More in ICSR])	<p>[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[NETAMETAMINE, NETAMETAMINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[ZOLPIDEM, ZOLPIDEM TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown])</p>	Not reported	ICSR
EU-EC-1000934018	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	<p>Anal fibrillation (27d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Death (1d - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000934038	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	<p>Death (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Fat (1d - Fatal - Results in Death),</p> <p>Feeling abnormal (1d - Fatal - Results in Death)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000934704	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	<p>Death (1d - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	<p>[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[PROZAC] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[SIBASTATIN] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown])</p>	Not reported	ICSR
EU-EC-1000934261	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-84 Years	Not Specified	Male	No	<p>Acute kidney injury (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Acute myocardial infarction (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Anal fibrillation (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Bandsaemia (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Cough (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Death (1d - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Dyspnoea (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Hypoxia (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Leukocytosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Lung consolidation (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Pneumonia (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Septic shock (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000934261	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-84 Years	Not Specified	Male	No	<p>Death (n/a - Fatal - Results in Death, Other Medically Important Condition)</p>	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	ANAVIVA (SITAGLIFTIN, SITAGLIFTIN PHOSPHATE, SITAGLIFTIN PHOSPHATE MONOHYDRATE) (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), <p>[ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[GLIMEPIRIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[SODORBIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[LEVOTHYRONINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[RISPERIDONE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]),</p> <p>[TIMOLOLEN, TIMOLOLEN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown])</p>	Not reported	ICSR

EU Local Number	EY Review Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Purpose	Literature Reference	Patient Age Group	Patient Sex (as per reporter)	Patient Sex	Patient Race	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Inert Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
												<p>(ACETYLSALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - 81mg - Unknown]).</p> <p>(CLINDAMYCIN, CLINDAMYCIN HYDROCHLORIDE, CLINDAMYCIN PHOSPHATE) (C - Product used for unknown indication - n/a - [n/a - 150mg - Unknown]).</p> <p>(CYANOCOBALAMIN, FOLIC ACID) (C - Product used for unknown indication - n/a - [n/a - 25000mg - Unknown]).</p> <p>(DL-ALPHA-TOCOPHEROL, ACETATE, RRR-ALPHA-TOCOPHEROL, FROM VEGETABLE OIL DISTILLATE, TOCOPHERYL ACETATE) (C - Product used for unknown indication - n/a - [n/a - 400mg - Unknown]).</p> <p>(DOUSATE SODIUM) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown).</p> <p>(FISH OIL) (C - Product used for unknown indication - n/a - [n/a - 15F] - Unknown).</p> <p>(METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPI) (C - n/a - n/a - [n/a - 15F] - Unknown).</p> <p>(METOPROLOL, METOPROLOL TARTRATE) (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]).</p> <p>(RABEPRAZOLE SODIUM) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown).</p> <p>(TAMELOSON HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - 41mg - Unknown]).</p> <p>(LUBICARENONE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown).</p>	
EU-EC-1000934372	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Cardiac failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Condition aggravated (14 - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000934493	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Myocardial infarction (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000934519	12/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	<p>(CFCOPRAZONE SODIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>(GLANTAMINE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>(IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>(LOSARTAN, LOSARTAN POTASSIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>(MRTAZAPINE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>(SALBUTAMOL, SALBUTAMOL SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),</p> <p>(VITAMIN D3) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])</p>	ICSR
EU-EC-1000934531	12/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (04 - Fatal - Results in Death, Other Medically Important Condition), Headache (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Pain (n/a - Unknown -), Pruritus (n/a - Unknown -), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	<p>(EUDINE) (SPRIBAN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(JANINA) (ESTRADIOL, ESTRADIOL VALERATE, ESTRADIOL MONOHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(CARVENOLOL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(FUROSEMIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(GLIPIZIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])</p>	ICSR
EU-EC-1000932616	10/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000931403	09/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Disorientation (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Alterations of vision (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Unknown)	Not reported	ICSR
EU-EC-1000931196	09/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Adverse reactions of vision (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000931306	09/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Agnosia (n/a - Unknown - Caused/Prolonged Hospitalisation), Anemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysstasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic function abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Hospitalisation (M - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Micturition disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), Suspected COVID-19 (n/a - Unknown -), Weight decreased (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	<p>(CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - Product used for unknown indication - n/a - [n/a - 75mg - Unknown]),</p> <p>(XARELTO) (RIVAROXABAN) (C - Product used for unknown indication - n/a - [n/a - 15mg - Unknown]),</p> <p>(AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE) (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]),</p> <p>(ROSUVASTATIN, ROSUVASTATIN CALCIUM) (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]),</p> <p>(SOTALOL, SOTALOL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])</p>	ICSR
EU-EC-1000931961	09/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cough (n/a - Not Recovered/Resolved -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Myalgia (n/a - Not Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	<p>(ACETYLSALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(LISINAPRIL, LISINAPRIL DIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(METOPROLOL, TARTRATE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(EMEPRAZOLE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(LUBICARENONE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown)</p>	ICSR
EU-EC-1000932605	09/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000932122	09/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Unknown - [n/a - 10F] - Unknown)	Not reported	ICSR
EU-EC-1000932242	09/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000932923	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abdominal distension (104 - Fatal - Results in Death), Abdominal pain (104 - Fatal - Results in Death), Atherosclerosis (104 - Fatal - Results in Death), Bronchial irritation (104 - Fatal - Results in Death), Coronary artery disease (104 - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (104 - Fatal - Results in Death), Emphysema (104 - Fatal - Results in Death), Enteritis (104 - Fatal - Results in Death), Eosinophilia (104 - Fatal - Results in Death), Hypertension (104 - Fatal - Results in Death), Myocardial fibrosis (104 - Fatal - Results in Death), Myocarditis (104 - Fatal - Results in Death, Other Medically Important Condition), Oedema (104 - Fatal - Results in Death), Urinoresonance to urinal (104 - Fatal - Results in Death, Other Medically Important Condition), Cardiac arrest (14 - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Syncope (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	<p>(FOLGITAZIONE) (PROGLITAZIONE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(APPLE CIDER VINEGAR) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(ATENOLOL, ATENOLOL BP) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(CINNAMON BARK) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(FENOFIBRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(GLIPIZIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(LISINAPRIL, LISINAPRIL DIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPI) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(NYSTATIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(VITAMINS NOS) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])</p>	ICSR
EU-EC-1000930306	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Urinoresonance to urinal (104 - Fatal - Results in Death, Other Medically Important Condition), Cardiac arrest (14 - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Syncope (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000930362	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000930922	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Brain oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombolytic (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	<p>(ACETYLSALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(ASCORBIC ACID) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(CYANOCOBALAMIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(FISH OIL) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(METOPROLOL, METOPROLOL, TARTRATE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(VITAMINS NOS) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(ZINC) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])</p>	ICSR
EU-EC-1000930166	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000930167	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Abdominal pain upper (104 - Fatal - Results in Death), Death (104 - Fatal - Results in Death, Other Medically Important Condition), Discomfort (104 - Fatal - Results in Death), Feeling abnormal (104 - Fatal - Results in Death), Vomiting (104 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	<p>(ATORVASTATIN CALCIUM) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(BICALUTAMIDE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(CYANOCOBALAMIN) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(FINASTERIDE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(FUROSEMIDE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(METOPROLOL, METOPROLOL, TARTRATE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p> <p>(PYRIDOXINE HYDROCHLORIDE, VITAMIN B6) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown)</p>	ICSR
EU-EC-1000930181	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000930252	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chest pain (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Colitis ischaemic (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (134 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ejection fraction decreased (134 - Fatal - Results in Death), Epigastric discomfort (134 - Fatal - Results in Death, Other Medically Important Condition), Thrombosis (134 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000930516	08/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000931603	08/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal pain (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anemia (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest pain (144 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Colitis ischaemic (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Constipation (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Coronary artery disease (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Epigastric discomfort (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Feeling cold (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Liver metastases (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia aspiration (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	<p>(GLYCYPYRROLUM BROMIDE) (C - Product used for unknown indication - n/a - [n/a - 4mg - Oral]),</p> <p>(HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE) (C - Prutiba - n/a - [n/a - 75mg - Oral]),</p> <p>(LISINAPRIL, LISINAPRIL DIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - 10mg - Oral]),</p> <p>(METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPI) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown)</p>	ICSR
EU-EC-1000928576	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	<p>(CYMBALTA) (DULOXETINE, DULOXETINE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - 10F] - Unknown),</p>	ICSR
EU-EC-1000928529	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Cerebrovascular accident (864 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000928798	07/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Pruritus (864 - Fatal - Results in Death), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Fluid intake reduced (n/a - Unknown - Caused/Prolonged Hospitalisation), Fluid overload (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Liver disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal impairment (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	<p>(AMTRIPYLLINE, AMTRIPYLLINE HYDROCHLORIDE) (C - Sleep disorder - n/a - [n/a - n/a - Oral]),</p> <p>(AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE) (C - Blood pressure management - n/a - [n/a - n/a - Oral]),</p> <p>(HYDROCODONE) (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]),</p> <p>(PARACETAMOL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p> <p>(POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])</p>	ICSR
EU-EC-1000928924	07/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Coronary artery thrombosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Ischaemic cardiomyopathy (n/a - Fatal - Results in Death, Other Medically Important Condition)	SPRIVIA (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - n/a - [n/a - 10F] - n/a))	<p>(ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIBHYDRATE) (C - n/a - n/a -)</p>	ICSR
EU-EC-1000929666	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Cardiac arrest (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (14 - Fatal - Results in Death, Other Medically Important Condition), Malaise (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000929795	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Alphasia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 10F] - Intramuscular)	<p>(ACETYLSALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),</p>	ICSR

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Child Report	Reaction List (PT - Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
										Aspiration (via - Not Recovered/Not Resolved - Other Medically Important Condition), Adhesion (via - Unknown -), Death (via - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (via - Unknown -), Dyspnoea (via - Unknown -), Fatigue (via - Unknown -), Feeding disorder (via - Unknown -), Haemoptysis (via - Unknown -), Hypoaemia (via - Unknown -), Laryngitis (via - Unknown -), Pyrexia (via - Unknown -), Throat irritation (via - Unknown -)	ascorbic - [via - 100mg - Intramuscular], (MENTHOL METHYL SALICYLATE) (S - Product used for unknown indication - via - [via - 100mg - Unknown]), COLECALCIFEROL (C - Product used for unknown indication - via - [via - 100mg - Unknown]), COLCICLUMIN (C - Product used for unknown indication - via - [via - 100mg - Unknown]), DYANODOLAMINE (C - Product used for unknown indication - via - [via - 100mg - Unknown]), METOPROLOL TARTRATE (C - Product used for unknown indication - via - [via - 5mg - Unknown]), PARACETAMOL (C - Product used for unknown indication - via - [via - 100mg - Unknown]), ROBUVASTATIN, ROBUVASTATIN CALCIUM (C - Product used for unknown indication - via - [via - 5mg - Unknown]), TERAZOSIN, TERAZOSIN HYDROCHLORIDE (C - Product used for unknown indication - via - [via - 5mg - Unknown]), LUBICARENONE (C - Product used for unknown indication - via - [via - 300mg - Unknown])		
EU-EC-1009298567	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (via - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Epistaxis (via - Fatal - Results in Death, Life Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-1009298981	07/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092973476	06/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (via - Unknown - Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Cardiac failure (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (via - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (via - Unknown - Caused/Prolonged Hospitalisation), Lung disorder (via - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (via - Recovered/Resolved -), Paresthesia (via - Unknown - Caused/Prolonged Hospitalisation), Phoritis (via - Unknown - Caused/Prolonged Hospitalisation), Rash (via - Unknown - Caused/Prolonged Hospitalisation), Renal failure (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-1009297308	06/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition), Dry mouth (via - Unknown -), Dyspnoea (via - Unknown -), Malaise (via - Unknown -), Thirst (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092979752	06/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death, Other Medically Important Condition), Product dose omission issue (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-1009296942	06/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	COVID-19 (via - Fatal - Results in Death, Life Threatening), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (via - Fatal - Results in Death), Diarrhoea (19d - Fatal - Results in Death), Hypoxia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (18d - Fatal - Results in Death), Malaise (25d - Fatal - Results in Death), Tremor (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092983122	06/07/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (via - Fatal - Results in Death, Other Medically Important Condition), Dizziness (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092983643	06/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Hut rash (via - Unknown -)	SPRIKAV (S - via - via - [via - via - via])	Not reported	ICSR
EU-EC-10092984897	06/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092985042	06/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	B-cell lymphoma (106d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (106d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (106d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lymphoma (106d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (106d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular] - More in ICSR)	TIKOSIN (DOFETILIDE) (C - Product used for unknown indication - via - [via - via - Unknown]), WARFARIN, WARFARIN SODIUM (C - Product used for unknown indication - via - [via - via - Unknown])	ICSR
EU-EC-10092985165	06/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	COLCHICINE (C - Product used for unknown indication - via - [via - via - via]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - via - [via - via - via])	ICSR
EU-EC-10092985919	06/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death, Other Medically Important Condition), Pulmonary embolism (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092987376	05/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Cardiac arrest (via - Fatal - Results in Death, Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (via - Fatal - Results in Death, Other Medically Important Condition), Resuscitation (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular] - More in ICSR)	COLECALCIFEROL, CALCIUM CITRATE (C - Product used for unknown indication - via - [via - 400µg - Unknown]), DOUCASATE SODIUM, CASAS (C - Product used for unknown indication - via - [via - 8.5mg - Unknown]), HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - via - [via - 25mg - Unknown]), LIMACITRINE (C - Product used for unknown indication - via - [via - 100mg - Unknown]), LINACLOTIDE (C - Product used for unknown indication - via - [via - via - Unknown]), PARACETAMOL (C - Product used for unknown indication - via - [via - 3000mg - Unknown]), PHENTYON (C - Product used for unknown indication - via - [via - 300mg - Unknown]), POTASSIUM CHLORIDE (C - Product used for unknown indication - via - [via - via - Unknown]), VITAMIN D (C - Product used for unknown indication - via - [via - 100µg - Unknown])	ICSR
EU-EC-10092981484	05/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	No	No	Depressed level of consciousness (via - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (1d - Fatal - Results in Death, Other Medically Important Condition), Stupor (1d - Fatal - Results in Death, Other Medically Important Condition)	SPRIKAV (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - via - via - via - via - via)	XARELTO 20 MG (RIVAROXABAN) (C - via - via - via - via - via), DOMPEPRIDONE, HYDROCHLORIDE (C - via - via -)	ICSR
EU-EC-10092989916	02/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (2d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular] - More in ICSR)	ACETYLSALICYLIC ACID (C - Product used for unknown indication - via - [via - 81mg - Oral]), DOUCASATE SODIUM (C - Product used for unknown indication - via - [via - 200mg - Oral]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - via - [via - 5mg - Oral]), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - via - [via - 100mg - Oral]), PARACETAMOL (C - Product used for unknown indication - via - [via - 3000mg - Oral])	ICSR
EU-EC-10092941625	02/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute respiratory failure (via - Fatal - Results in Death, Other Medically Important Condition), Ankle swelling (via - Fatal - Results in Death), Atrial enlargement (via - Fatal - Results in Death), Cardiac arrest (via - Fatal - Results in Death, Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Gibberish disorder (via - Fatal - Results in Death), Hypoxia (via - Fatal - Results in Death, Other Medically Important Condition), Lung consolidation (via - Fatal - Results in Death), Multiple organ dysfunction syndrome (via - Fatal - Results in Death, Other Medically Important Condition), Neurological decompensation (via - Fatal - Results in Death), Pulmonary embolism (via - Fatal - Results in Death, Other Medically Important Condition), Pulmonary infarction (via - Fatal - Results in Death, Other Medically Important Condition), Renal cyst (via - Fatal - Results in Death), Shock (via - Fatal - Results in Death, Other Medically Important Condition), Ventricular enlargement (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	ACETYLSALICYLIC ACID (C - Product used for unknown indication - via - [via - 81mg - Oral]), DOUCASATE SODIUM (C - Product used for unknown indication - via - [via - 200mg - Oral]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - via - [via - 5mg - Oral]), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - via - [via - 100mg - Oral]), PARACETAMOL (C - Product used for unknown indication - via - [via - 3000mg - Oral]), ATEKOL, ATROVASTATIN (C - Product used for unknown indication - via - [via - 50mg - Unknown]), FLUTICASON, PROPIONATE (C - Product used for unknown indication - via - [via - 100µg - Unknown]), HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - via - [via - 50mg - Unknown]), LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - via - [via - 100mg - Unknown]), PAROXETINE, PAROXETINE HYDROCHLORIDE, PAROXETINE HYDROCHLORIDE, ANHYDROUS (C - Product used for unknown indication - via - [via - 40mg - Unknown]), TRAZODONE, TRAZODONE HYDROCHLORIDE (C - Product used for unknown indication - via - [via - 200mg - Unknown])	ICSR
EU-EC-10092941891	02/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Ventricular enlargement (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092941930	02/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Abdominal discomfort (3d - Fatal - Results in Death), Asthma (2d - Fatal - Results in Death), Chills (2d - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Vomiting (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	BUMETANIDE, BUMETANIDE (C - Product used for unknown indication - via - [via - via - Unknown]), MULTAQ (DROMEDARONE) (C - Product used for unknown indication - via - [via - via - Unknown]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - via - [via - via - Unknown]), BRIMONIDE, BRIMONIDE TARTRATE (C - Product used for unknown indication - via - [via - via - Unknown]), CALCIUM CARBONATE, COLECALCIFEROL, CONCENTRATE (POWDER FORM), COLECALCIFEROL, CALCIUM CARBONATE (C - Product used for unknown indication - via - [via - via - Unknown]), COLECALCIFEROL (C - Product used for unknown indication - via - [via - via - Unknown]), DEXTRIN (C - Product used for unknown indication - via - [via - via - Unknown]), HYDROCODONE (C - Product used for unknown indication - via - [via - via - Unknown]), LANTANOPROST (C - Product used for unknown indication - via - [via - via - Unknown]), LIDOCANE, LIDOCANE HYDROCHLORIDE (C - Product used for unknown indication - via - [via - via - Unknown]), NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE (C - Product used for unknown indication - via - [via - via - Unknown]), DAPRIZOLE (C - Product used for unknown indication - via - [via - via - Unknown]), PARACETAMOL (C - Product used for unknown indication - via - [via - via - Unknown]), POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - via - [via - via - Unknown]), PRAMPEXOLE, PRAMPEXOLE DIHYDROCHLORIDE MONOHYDRATE (C - Product used for unknown indication - via - [via - via - Unknown]), AMOXICILIN, AMOXICILIN HYDROCHLORIDE (C - Product used for unknown indication - via - [via - via - via]), HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - via - [via - via - via])	ICSR
EU-EC-10092942595	02/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Pain (3d - Fatal - Results in Death), Snooring (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular] - More in ICSR)	AMOXICILIN SODIUM, POTASSIUM CLAVULANATE, AMOXICILIN, CLAVULANIC ACID (C - Ear infection - via - [via - via - Oral]), DEFUROXIME, DEFUROXIME AXETIL (C - Ear infection - via - [via - via - Unknown])	ICSR
EU-EC-10092943527	02/07/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	SPRIKAV (S - via - via - [via - via - via])	Not reported	ICSR
EU-EC-10092943070	02/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092947205	02/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (2d - Fatal - Results in Death, Other Medically Important Condition), Hypertensive heart disease (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092926035	01/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death), Headache (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Movement disorder (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular] - More in ICSR)	Not reported	ICSR
EU-EC-10092927908	01/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	No	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092920321	01/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Drug interaction (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	RITUXIMAB (C - Product used for unknown indication - via - [via - via - Unknown])	ICSR
EU-EC-10092920676	01/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-1009291843	01/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Respiratory arrest (via - Unknown - Other Medically Important Condition), Seizure (via - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	BETAMETHASONE, BETAMETHASONE DIPROPIONATE (C - Product used for unknown indication - via - [via - 100µg - Unknown]), COLECALCIFEROL (C - Product used for unknown indication - via - [via - 100µg - Unknown]), NYSTATIN, NYSTATIN, ZINC OXIDE (C - Product used for unknown indication - via - [via - 100µg - Unknown])	ICSR
EU-EC-1009292104	01/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebrovascular accident (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092923166	01/07/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death)	SPRIKAV (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - Immunisation - via - [via - via - via])	Not reported	ICSR
EU-EC-10092923976	01/07/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cerebrovascular accident (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR
EU-EC-10092920326	20/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Mental status changes (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation) Death (0d - Fatal - Results in Death, Other Medically Important Condition), Disease progression (via - Fatal - Results in Death)	SPRIKAV (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	HUMALOG (INSULIN LISAPRO) (C - Product used for unknown indication - Dose not changed - [via - 100µg - Subcutaneous]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - Dose not changed - [via - 100mg - Oral - More in ICSR]), ALUMINIUM OXIDE, HYDRATED, MAGNESIUM HYDROXIDE (C - Product used for unknown indication - Dose not changed - [via - 30mg - Oral]), ATORVASTATIN (C - Product used for unknown indication - Dose not changed - [via - 30mg - Oral]), CALCIUM (C - Product used for unknown indication - Dose not changed - [via - 75mg - Oral]), FOLIC ACID (C - Product used for unknown indication - Dose not changed - [via - 5mg - Oral]), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Product used for unknown indication - Dose not changed - [via - 100µg - Oral]), MAGNESIUM ASPARTATE HYDROCHLORIDE (C - Product used for unknown indication - Dose not changed - [via - 125.5mg - Oral]), METOLAZONE (C - Product used for unknown indication - Dose not changed - [via - 5mg - Oral]), METOPROLOL, SUCCINATE (C - Product used for unknown indication - Dose not changed - [via - 50mg - Oral]), DUMESARTAN MEDOXIMIL (C - Product used for unknown indication - Dose not changed - [via - 40mg - Oral]), TORASEMIDE, TORASEMIDE SODIUM (C - Product used for unknown indication - Dose not changed - [via - 200mg - Oral]), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - Product used for unknown indication - via - [via - via - via]), ELIQUIS (APIXIBAN) (C - Product used for unknown indication - via - [via - via - via]), PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - Product used for unknown indication - via - [via - via - via]), ACICLOVIR SODIUM (C - Product used for unknown indication - via - [via - via - via]), ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM (C - Product used for unknown indication - via - [via - via - via]), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - Product used for unknown indication - via - [via - via - via]), CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE (C - Product used for unknown indication - via - [via - via - via]), LILLOXAMINE, CHONDROITIN (C - Product used for unknown indication - via - [via - via - via]), METOPROLOL, METOPROLOL, TARTRATE (C - Product used for unknown indication - via - [via - via - via]),	ICSR
EU-EC-10092912853	20/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 100µg - Intramuscular])	Not reported	ICSR

EU Local Number	EY Review Period	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Chirality	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Involved Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-1000214475	30/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), APKABAN (APKABAN) (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), HUMALOG (INSULIN LISPRO) (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), LEVETIRACETAM (LEVETIRACETAM) (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), ASCORBIC ACID (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), CHLORHEXIDINE (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), COLLAGENASE CLOSTRIDIUM HISTOLYTICUM (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), DUCOSATE (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), SALBUTAMOL SULFATE, (PRATAPLUM BROMIDE) (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), SODIUM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), TRAMADOL, TRAMADOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), ZINC (C - Product used for unknown indication - n/a - [10a - n/a - n/a])	ICSR
EU-EC-100021626	30/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Unknown)	Not reported	ICSR
EU-EC-1000217080	30/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Blindness (14 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (14 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Seizure (14 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular - More in ICSR)	BUPROPION HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), GABAPENTIN (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), PARACETAMOL (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), PRAMIPROXOLINE, PRAMIPROXOLINE DIHYDROCHLORIDE MONOHYDRATE (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), SERTRALINE, SERTRALINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), BUPROPION, BUPROPION NANOERGEN SODIUM (C - Product used for unknown indication - n/a - [10a - n/a - Unknown]), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [10a - n/a - Unknown])	ICSR
EU-EC-1000217140	30/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Infection (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia haemorrhagic (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia pseudomonas (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sepsis (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000219601	30/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (14 - Fatal - Results in Death), Unresponsive to stimuli (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000198904	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000198621	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [10F] - Intramuscular)	ABIFY (ABIRPRAZOLE) (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), MIRABEGRON (MIRABEGRON) (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), CASSIA (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), DOLICALCIFEROL (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), MACROGOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350 (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), MIZAPATINE (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), MORPHINE SULFATE (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), PARACETAMOL (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), TAMBULOSIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown)	ICSR
EU-EC-1000198696	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Unknown)	Not reported	ICSR
EU-EC-1000198725	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Unknown)	Not reported	ICSR
EU-EC-1000198692	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Vaccination complication (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000198718	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac arrest (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Ventricular fibrillation (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [10F] - Intramuscular)	TOCOPHEROL (TOCOPHEROL) (C - Product used for unknown indication - n/a - [10a - 150mg - Unknown]), ATORVASTATIN (C - Product used for unknown indication - n/a - [10a - 10mg - Unknown]), DOLICALCIFEROL, CALCIUM (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - n/a - [10a - 25mg - Unknown]), POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [10a - 98mg - Unknown]), TITANIUM DIOXIDE (C - Product used for unknown indication - n/a - [10a - n/a - Unknown])	ICSR
EU-EC-1000198724	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000198763	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Compartment syndrome (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis shock (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	MYCOPHENOLATE MOFETIL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - 500mg - Oral]), INFEDIPINE (C - Product used for unknown indication - n/a - [10a - 60mg - Oral]), DMIPRAZOLE (C - Product used for unknown indication - n/a - [10a - 40mg - Oral])	ICSR
EU-EC-1000198747	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac arrest (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular - More in ICSR)	AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [10a - n/a - Unknown]), ATORVASTATIN (C - Product used for unknown indication - n/a - [10a - n/a - Unknown]), HYDROCHLOROTHIAZIDE, LOSARTAN, LOSARTAN POTASSIUM, HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - n/a - [10a - n/a - Unknown])	ICSR
EU-EC-1000198815	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000198820	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chills (8F - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (14 - Fatal - Results in Death), Dizziness (14 - Fatal - Results in Death), Dyspnoea (14 - Fatal - Results in Death), Oropharyngeal pain (14 - Fatal - Results in Death), Pain (14 - Fatal - Results in Death), Pyrexia (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Unknown)	Not reported	ICSR
EU-EC-1000198913	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Pyrexia (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [10a - 81mg - Unknown]), ALPHATOCOPHEROL ACETATE, LUTENIN (C - Product used for unknown indication - n/a - [10a - n/a - Unknown]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [10a - n/a - Unknown]), CALCIUM (C - Product used for unknown indication - n/a - [10a - 25mg - Unknown]), ERGOCALCIFEROL (C - Product used for unknown indication - n/a - [10a - 125mg - Unknown]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [10a - 5mg - Unknown])	ICSR
EU-EC-1000198932	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung disorder (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary granuloma (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Syncope (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000199047	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Unknown)	METHADONE (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown)	ICSR
EU-EC-1000199274	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Unknown)	Not reported	ICSR
EU-EC-1000199365	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Hepatic cancer (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000199178	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Neck pain (14 - Fatal - Results in Death)	SPIREVA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [10F] - n/a)	Not reported	ICSR
EU-EC-1000194693	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Oropharyngeal pain (14 - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000194795	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal pain (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [10F] - Intramuscular)	CARBIDOPA, LEVODOPA (CARBIDOPA, LEVODOPA) (C - Product used for unknown indication - n/a - [10a - n/a - Unknown]), ENTACAPONE (ENTACAPONE) (C - Product used for unknown indication - n/a - [10a - 200mg - Unknown]), BUPROPION (BUPROPION, BUPROPION SODIUM) (C - Product used for unknown indication - n/a - [10a - 300mg - Unknown]), FLUTICASON PROPIONATE (C - Product used for unknown indication - n/a - [10a - n/a - Unknown]), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BIF (C - Product used for unknown indication - n/a - [10a - n/a - Unknown])	ICSR
EU-EC-1000197598	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chest pain (34 - Fatal - Results in Death), Death (34 - Fatal - Results in Death, Other Medically Important Condition), Fatigue (34 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Drug withdrawn - [10a - 10F] - n/a)	Not reported	ICSR
EU-EC-1000197813	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	SPIREVA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Drug withdrawn - [10a - 10F] - n/a)	Not reported	ICSR
EU-EC-1000197934	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), FEXOFENADINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), FENASTERIN (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), MIRABEGRON (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), MONTELUKAST, MONTELUKAST SODIUM (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), PROMETHAZINE, PROMETHAZINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), SIMVASTATIN (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown), TOLTERODINE (C - Product used for unknown indication - n/a - [10a - 10F] - Unknown)	ICSR
EU-EC-1000198119	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chills (26 - Fatal - Results in Death), Cough (26 - Fatal - Results in Death), Death (26 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (26 - Fatal - Results in Death), Pyrexia (26 - Fatal - Results in Death), Vaccination site pain (26 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000198074	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardio-respiratory arrest (14 - Fatal - Results in Death, Other Medically Important Condition), Condition aggravated (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Embolism (14 - Fatal - Results in Death, Other Medically Important Condition), Fatigue (14 - Fatal - Results in Death), Hypertension (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Unknown)	Not reported	ICSR
EU-EC-1000199040	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000191434	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Aortic aneurysm repair (14 - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (14 - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (14 - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (14 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	BUMETANIDE (BUMETANIDE) (C - Product used for unknown indication - n/a - [10a - 1mg - n/a]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), ASCORBIC ACID (C - Product used for unknown indication - n/a - [10a - n/a - n/a]), ATORVASTATIN (C - Product used for unknown indication - n/a - [10a - 40mg - n/a]), EZETIMIBE (C - Product used for unknown indication - n/a - [10a - 10mg - n/a]), HYDRALAZINE (C - Product used for unknown indication - n/a - [10a - 100mg - n/a]), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Product used for unknown indication - n/a - [10a - 50ug - n/a]), LINCLOTHIDE (C - Product used for unknown indication - n/a - [10a - 145ug - n/a]), LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [10a - 50mg - n/a]), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [10a - 50mg - n/a]), TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [10a - 4mg - n/a]), URBICARENONE (C - Product used for unknown indication - n/a - [10a - n/a - n/a])	ICSR
EU-EC-1000191899	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac arrest (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000192009	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac arrest (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Fatigue (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000192458	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000193321	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac failure acute (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	SPIREVA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000193853	29/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [10F] - Intramuscular)	Not reported	ICSR
EU-EC-1000197760													

EU Local Number	EV Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Status	Parent	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
										Chest discomfort (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	applicable - [n/a - 1(DP) - Unknown]	FLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FUROSEMIDE, FUROSEMIDE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [INSULIN HUMAN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000919362	26/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diarrhoea (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Duodenitis (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lactacystosis (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Toxicity to various agents (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - More in ICSR])	None reported	ICSR
EU-EC-1000914267	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Fat (50 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[EMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-10009147136	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (04 - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	ZYLIT (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - n/a - n/a - [n/a - 75mg - Oral]), [COLCICALCIFEROL] (C - n/a - n/a - [n/a - n/a - Oral]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM ESOMEPRAZOLE MAGNESIUM DIHYDRATE] (C - n/a - n/a - [n/a - 20mg - Oral]), FUROSEMIDE (C - n/a - n/a - [n/a - 20mg - Oral]), POTASSIUM CHLORIDE (C - n/a - n/a - [n/a - 600mg - Oral])	ICSR
EU-EC-10009147765	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Fatigue (314 - Fatal - Results in Death), Lethargy (314 - Fatal - Results in Death), Migraine (314 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	LYRICA (PREGABALIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ESTROGENS CONJUGATED, ESTROGEN SODIUM SULFATE, EQUIN SULFATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DIXYCODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DIXYCODONE, DIXYCODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PARACETAMOL, ACETYL SALICYLIC ACID, CAFFEINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-1000919194	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	None reported	ICSR
EU-EC-1000915329	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (14 - Fatal - Results in Death), Lethargy (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	None reported	ICSR
EU-EC-1000915336	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	None reported	ICSR
EU-EC-10009154495	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	None reported	ICSR
EU-EC-10009154751	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	ELIQUIS (APIXIBAN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DIOXIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009156484	25/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	[CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Oral]), [FLUCONAZOLE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Topical]), FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), HYDROCORTISONE (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Oral]), POTASSIUM CHLORIDE (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Oral])	ICSR
EU-EC-10009124144	24/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Anemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Depressed appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), HCV/OC43 infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypersaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Orthostatic hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral T-cell lymphoma unspecified (n/a - Fatal - Results in Death, Other Medically Important Condition), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory symptom (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Oral]), [ANTIPYRAXOLE, PANTOPRAZOLE SODIUM BESILATE] (C - Product used for unknown indication - Unknown - [n/a - 1(DP) - Unknown]), [ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM CALCIUM GLUBONATE, CALCIUM CARBONATE, COLCICALCIFEROL, CALCIUM] (C - Product used for unknown indication - Unknown - [n/a - 1(DP) - Unknown]), [HYDROXYCHLOROQUINE] (C - Product used for unknown indication - Unknown - [n/a - 1(DP) - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - Unknown - [n/a - 1(DP) - Unknown]), [PLOCARPINE, PLOCARPINE HYDROCHLORIDE] (C - Product used for unknown indication - Unknown - [n/a - 1(DP) - Unknown])	ICSR
EU-EC-10009138439	24/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Pyrexia (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	None reported	ICSR
EU-EC-10009142526	24/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Acute Ironitoxosis (21 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain venous sinus thrombosis (21 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (23 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neurological symptom (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Peripheral artery thrombosis (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[MELGAPRANTIDE] (C - Product used for unknown indication - n/a - [n/a - 80mg - Subcutaneous]), [COLISTEPTIL] (C - Product used for unknown indication - n/a - [n/a - 2g - Unknown]), [FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [SABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [HYDROMORPHONE] (C - n/a - n/a - [n/a - 4mg - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BIF] (C - Product used for unknown indication - n/a - [n/a - 1000mg - Unknown]), [VENAFAXINE, VENAFAXINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown])	ICSR
EU-EC-10009112537	23/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Inappropriate schedule of product administration (14 - Recovered/Resolved -), Vaccination site pain (84 - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - More in ICSR)	None reported	ICSR
EU-EC-10009113306	23/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	No	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	None reported	ICSR
EU-EC-10009118995	23/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Loss of consciousness (14 - Fatal - Results in Death, Other Medically Important Condition), Myalgia (14 - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (14 - Fatal - Results in Death, Other Medically Important Condition)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[INSULIN HUMAN (INSULIN HUMAN)] (C - Product used for unknown indication - Dose not changed - [n/a - 2mg - Unknown]), LYRICA (PREGABALIN) (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), TREBBA (INSULIN DEGLUDEC) (C - Product used for unknown indication - Dose not changed - [n/a - 600(DP) - Unknown]), VICTOZA (LIRAGLUTIDE) (C - Product used for unknown indication - Dose not changed - [n/a - 12mg - Unknown]), [ACEINOCUMAROL] (C - Product used for unknown indication - Dose not changed - [n/a - 1mg - Unknown]), [FLUCONAZOLE, FLUCONAZOLE ACETATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [SULCASON, SULCASON HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), [SULCIEN, TRINITRILE] (C - Chest pain - n/a - [n/a - 200(DP) - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - Dose not changed - [n/a - 20mg - Unknown]), [LORAZEPAM] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), [METOPROLOL, SUCCINATE, METOPROLOL TARTRATE] (C - Product used for unknown indication - Dose not changed - [n/a - 100mg - Unknown]), [PANTOPRAZOLE] (C - Product used for unknown indication - Dose not changed - [n/a - 20mg - Unknown])	ICSR
EU-EC-10009120747	23/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Acute kidney injury (94 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	None reported	ICSR
EU-EC-10009121149	23/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Hematuria (99 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General thrombosis (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mechanical ventilation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	[HEMALOG] (INSULIN LISAPRO) (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [URDANIS] (EMPAGLIFLOZIN) (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [LANTUS (INSULIN GLARGINE)] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [TACROLIMUS (TACROLIMUS, TACROLIMUS MONOHYDRATE)] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [TRILICITY (DUALAGLUTIDE)] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [CALCIOTROL] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [FISH OIL] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [MYCOPHENOLATE SODIUM, MYCOPHENOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [EMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [PREDNISONE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [SIMVASTATIN, EZETIMIBE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [SULAMETHOXAZOLE, TRIMEPRIM] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [FRAMBULGIN, FRAMBULGIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [VITAMIN NOS] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown])	ICSR
EU-EC-10009121255	23/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypertension (54 - Fatal - Results in Death), Pain (54 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	None reported	ICSR
EU-EC-10009121341	23/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebrovascular accident (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - More in ICSR])	None reported	ICSR
EU-EC-10009123370	23/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	None reported	ICSR
EU-EC-10009123305	23/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Asthma (2m - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebrovascular accident (2m - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dizziness (2m - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (2m - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Incorrect dose administered (14 - Recovered/Resolved -), Somnolence (2m - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vision blurred (2m - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	[SABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [FRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown])	ICSR
EU-EC-10009103438	22/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	None reported	ICSR
EU-EC-10009106779	22/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Breast abnormal (n/a - Unknown -), Breast (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	None reported	ICSR
EU-EC-10009106020	22/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Acute kidney injury (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Other Medically Important Condition), General physical health deterioration (n/a - Unknown -), Hypoxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Other Medically Important Condition), Respiratory distress (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vagina pruritus (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular - More in ICSR])	FLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - 75mg - Unknown]), [ALFUZOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [AMLODIPINE, AMLODIPINE BESILATE] (C - Product used for unknown indication - n/a - [n/a - 2.5mg - Unknown]), [DESVENLAFAXINE SUCCINATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 500mg - Unknown]), [VITAMIN D, CALCIUM] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown])	ICSR
EU-EC-10009094520	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Angina pectoris (n/a - Unknown - Other Medically Important Condition), Asthma (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Heart rate irregular (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	None reported	ICSR
EU-EC-10009094761	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (14 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	None reported	ICSR
EU-EC-10009094763	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Foaming at mouth (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	None reported	ICSR
EU-EC-10009094764	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Mistake (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	None reported	ICSR
EU-EC-10009094762	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Blind pain (764 - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Inflammation (764 - Unknown - Other Medically Important Condition), Sciatica (764 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	ELIQUIS (APIXIBAN) (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [COLC	

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Race	Parent Child Report	Reaction List PT (Duration) ? Outcome - Seriousness Criteria	Supplementing Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
EU-EC-100098523	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute myocardial infarction (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098518	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098561	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098566	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Arrhythmia (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Seizure (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[CARIPRAZINE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [CLONIDINE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [LISINAPRIL/PERINDAPRIL] (C - Product used for unknown indication - n/a - [via - n/a - Unknown])	ICSR	
EU-EC-100098620	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100098689	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [FERRUS SULFATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [METFORMIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [TAMUSOLON HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown])	ICSR	
EU-EC-100098742	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular - More in ICSR)	[FRAMOXOL, FRAMOXOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - 3mg - Unknown]), [CLONAZEPAM] (C - Product used for unknown indication - n/a - [via - 3mg - Unknown]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [via - 25mg - Unknown]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Product used for unknown indication - n/a - [via - 10mg - Unknown])	ICSR	
EU-EC-100098757	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Acute kidney injury (via - Fatal - Results in Death, Other Medically Important Condition), COVID-19 (via - Fatal - Results in Death), Death (via - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (via - Unknown -), Dyspnoea (via - Fatal - Results in Death), Hypoxemia (via - Fatal - Results in Death), Pneumonia (via - Fatal - Results in Death, Other Medically Important Condition), Respiratory distress (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098760	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[ACEFOLIC ACID, ASPIRIN BP] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [DIAZEPAM] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [VITAMIN K2] (C - Product used for unknown indication - n/a - [via - n/a - n/a])	ICSR	
EU-EC-1000988103	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (15 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypovolaemia (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-100098981	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (334 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000990282	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intracardiac thrombus (134 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (134 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000990593	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular - More in ICSR)	Not reported	ICSR	
EU-EC-100099261	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (224 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (224 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (224 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (224 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (224 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-100099239	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000992941	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute respiratory failure (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Atrial fibrillation (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac failure chronic (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ejection fraction decreased (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Follicular lymphoma (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000993056	21/06/2021	Spontaneous	Not Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abdominal pain upper (via - Unknown -), Back pain (via - Unknown -), Death (via - Fatal - Results in Death, Other Medically Important Condition), Headache (via - Unknown -), Hospitalisation (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000994548	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[LANTUS (INSULIN GLARGINE)] (C - Product used for unknown indication - n/a - [via - 10U] - Unknown), [PHENYTOIN] (C - Product used for unknown indication - n/a - [via - 100mg - Unknown]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Product used for unknown indication - n/a - [via - 50mg - Unknown]), [ITEMAZEPAM] (C - Product used for unknown indication - n/a - [via - 30mg - Unknown]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [via - 50mg - Unknown]), [BIMASTATIN] (C - Product used for unknown indication - n/a - [via - 40mg - Unknown])	ICSR	
EU-EC-1000994712	21/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Feeling abnormal (24 - Fatal - Results in Death, Other Medically Important Condition), Malaise (24 - Fatal - Results in Death, Other Medically Important Condition), Death (via - Fatal - Results in Death, Other Medically Important Condition), Seizure (via - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000994796	21/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000991223	20/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	COVID-19 (84 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (84 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (84 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (84 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[CELCEPT (MYCOPHENOLATE MOFETIL)] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [TACROLIMUS (TACROLIMUS MONOHYDRATE)] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [CICLOSPORIN] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [PREDNISONE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown)	ICSR	
EU-EC-1000991227	20/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[ENTRESTO (VALSARTAN, SACUBITRIL)] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [ACEFOLIC ACID] (C - Product used for unknown indication - n/a - [via - 81mg - n/a]), [BIOTIN] (C - Product used for unknown indication - n/a - [via - 10P] - Unknown), [CALCIUM ACETATE] (C - Product used for unknown indication - n/a - [via - 200mg - n/a]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [via - 50mg - Unknown]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [via - 1mg - Unknown]), [HYDROMORPHONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - 8mg - Oral]), [ACEFOLIC ACID] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [ALLOPURINOL] (C - Product used for unknown indication - n/a - [via - 300mg - Unknown]), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY MAGNESIUM] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [BUFENORAC, BUFENORAC MONOHYDRATE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN LACTATE] (C - Product used for unknown indication - n/a - [via - 500mg - Unknown]), [COLCHICINE] (C - Product used for unknown indication - n/a - [via - 6mg - Unknown]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [PARACETAMOL] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [PROMETHAZINE, PROMETHAZINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [SALBUTAMOL SULFATE, (PRATROPIUM BROMIDE)] (C - Product used for unknown indication - n/a - [via - n/a - Nasal]), [TRIMETHOPRIM LACTATE, SULFAMETHOXAZOLE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown)	Not reported	ICSR
EU-EC-1000991421	20/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (574 - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (574 - Fatal - Results in Death), Dehydration (574 - Fatal - Results in Death), General physical health deterioration (574 - Fatal - Results in Death), Hives (574 - Fatal - Results in Death), Immediate post injection reaction (574 - Fatal - Results in Death), Malnutrition (574 - Fatal - Results in Death), Staphylococcal sepsis (574 - Fatal - Results in Death, Other Medically Important Condition), Weight decreased (574 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000991755	19/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (via - Unknown - Caused/Prolonged Hospitalisation), Ischaemic stroke (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000991028	19/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000991139	18/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[IRON (IRON)] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [MELTONGIN (MELTONGIN)] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [COD-LIVER OIL] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [ERDOCALCIFEROL] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [LONAZEPAM] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown)	Not reported	ICSR
EU-EC-1000992623	18/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial infarction (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000992624	18/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000971365	18/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (117min - Fatal - Results in Death, Other Medically Important Condition), Oxygen saturation decreased (117min - Fatal - Results in Death), Rates (117min - Fatal - Results in Death), Respiratory tract congestion (117min - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000972557	18/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Fatigue (24 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[EUGIUS (PRAZOSIN)] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUITERTRATE)] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [ALCOPRINE, ALCOPRINE BESILATE, ALCOPRINE MALATE, ALCOPRINE MESILATE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [COLCHICINE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [ARRIPRAZOLE (ARRIPRAZOLE)] (C - Product used for unknown indication - n/a - [via - 20mg - Unknown]), [AMTRIPTYLINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - 50mg - Unknown]), [ALCOPRINE BESILATE] (C - Product used for unknown indication - n/a - [via - 5mg - Unknown]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [via - 1mg - Unknown]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [via - 20mg - Unknown]), [OMEPRAZOLE] (C - Product used for unknown indication - n/a - [via - 40mg - Unknown]), [RITINOL] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown), [SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown)	Not reported	ICSR
EU-EC-100097266	18/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Aspiration (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (via - Unknown - Caused/Prolonged Hospitalisation), Cough (via - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysphagia (via - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (via - Unknown - Caused/Prolonged Hospitalisation), Internal haemorrhage (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000973364	18/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000984856	17/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (64 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000984243	17/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Injection site pain (14 - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (14 - Fatal - Results in Death, Other Medically Important Condition), Vomiting (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [via - 1DP] - Unknown)	ICSR	
EU-EC-1000985065	17/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute respiratory failure (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Angina pectoris (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardogenic shock (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic failure (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (via - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-			

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Infecting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-100093604	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100093672	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM), COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE) (C - Product used for unknown indication - Not applicable - [n/a - 1DP] - Oral), [CHONDROITIN SULFATE, CHONDROITIN SULFATE SODIUM] (C - Product used for unknown indication - Not applicable - [n/a - 800mg - Oral]), [DIPOTASSIUM CLORAZEPATE] (C - Product used for unknown indication - Not applicable - [25d 5mg - Oral]), [FOLIC ACID] (C - Product used for unknown indication - Not applicable - [25d 5mg - Oral]), [GINSO BLOSSA] (C - Product used for unknown indication - Not applicable - [n/a - 240mg - Oral]), [HYALURONIC ACID] (C - Product used for unknown indication - Not applicable - [n/a - 1DP] - Intramuscular), [LORAZEPAM] (C - Product used for unknown indication - Not applicable - [n/a - 3mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - Product used for unknown indication - Not applicable - [n/a - 1000mg - Oral]), [OLANZAPINE] (C - Product used for unknown indication - Not applicable - [n/a - 20mg - Oral]), [PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE HEMHYDRATE] (C - Product used for unknown indication - Not applicable - [n/a - 2000mg - Oral]), [PAROXETINE HYDROCHLORIDE, ANHYDROUS] (C - Product used for unknown indication - Not applicable - [n/a - 40mg - Oral]), [POTASSIUM SODIUM MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Product used for unknown indication - Not applicable - [n/a - 1DP] - Oral), [THIAMINE HYDROCHLORIDE] (C - Product used for unknown indication - Not applicable - [n/a - 300mg - Oral]), [TOPIRAMATE] (C - Product used for unknown indication - Not applicable - [n/a - 150mg - Oral]), [VALERIAN ROOT EXTRACT, VALERIANAE RADIX EXTRACT, LUPULI STROBILI EXTRACTUM SICCUM] (C - Product used for unknown indication - Not applicable - [n/a - 250mg - Oral]), [ZOLPIDEM, ZOLPIDEM HEMITARTRATE, ZOLPIDEM TARTRATE] (C - Product used for unknown indication - Not applicable - [n/a - 10mg - Oral])	ICSR
EU-EC-100094287	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	ESICATOPRAM, ESCITALOPRAM OXALATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100094316	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Fatal - Results in Death), Eye movement disorder (n/a - Fatal - Results in Death), Fat (n/a - Fatal - Results in Death), Injection site pain (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Nervousness (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Seizure like phenomena (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100094363	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-100094472	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Fatal - Results in Death, Life Threatening), Asthma (n/a - Fatal - Results in Death), Asthma (n/a - Fatal - Results in Death, Life Threatening), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Fatal - Results in Death, Life Threatening), Fatigue (n/a - Fatal - Results in Death, Life Threatening), Hypersomnia (n/a - Fatal - Results in Death, Life Threatening), Large intestine perforation (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100095234	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100095209	15/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Condition aggravated (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Disease recurrence (n/a - Unknown -), Gastritis (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100095952	15/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100096056	15/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000961326	15/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000961251	14/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Adult	Male	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000961171	12/06/2021	Spontaneous	Not Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Agitation (n/a - Recovering/Resolving -), Asthma (n/a - Recovering/Resolving -), Clefts (n/a - Recovering/Resolving -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pain (n/a - Recovering/Resolving -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000961199	11/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fat (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR
EU-EC-100096205	11/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Yes	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR
EU-EC-100096062	11/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - n/a]), XARELTO [RIVAROXABAN] (C - Product used for unknown indication - Dose not changed - [n/a - 10mg - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - n/a]), [FERRIC HYDROXIDE POLYMALTOSE COMPLEX, IRON, IRON(III) ION] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - Not changed - [n/a - n/a - n/a]), [PREDNISOLONE] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - n/a]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE MONOHYDRATE] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - n/a]), [TORSEMIDE] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - n/a])	ICSR
EU-EC-1000961721	11/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthma (16d - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fat (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ALLOPURINOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FERROUS SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SABAFENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LINALPITIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SPRONOLACTONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BIOTIN, CALCIUM PANTOTHENATE, CYANOCOBALAM, NICOTINAMIDE, PYRIDOXINE, RIBOFLAVIN, THIAMINE NITRATE, BIOTIN, CALCIUM PANTOTHENATE, NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, VITAMIN B12] (C - Product used for unknown indication - n/a - [n/a - 1DP] - Oral), [BISOPROLOL, FUMARATE, BISOPROLOL, FUMARATE, ACETYLSALICYLIC ACID, BISOPROLOL, HEMIFUMARATE] (C - Product used for unknown indication - n/a - [n/a - 1.25mg - Oral]), [BROMAZEPAM] (C - Product used for unknown indication - n/a - [n/a - 1.5mg - Oral]), [CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM), COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral]), [SIBNASTATIN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral])	ICSR
EU-EC-1000962187	11/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac failure (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Headache (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[FAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BIOTIN, CALCIUM PANTOTHENATE, CYANOCOBALAM, NICOTINAMIDE, PYRIDOXINE, RIBOFLAVIN, THIAMINE NITRATE, BIOTIN, CALCIUM PANTOTHENATE, NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, VITAMIN B12] (C - Product used for unknown indication - n/a - [n/a - 1DP] - Oral), [BISOPROLOL, FUMARATE, BISOPROLOL, FUMARATE, ACETYLSALICYLIC ACID, BISOPROLOL, HEMIFUMARATE] (C - Product used for unknown indication - n/a - [n/a - 1.25mg - Oral]), [BROMAZEPAM] (C - Product used for unknown indication - n/a - [n/a - 1.5mg - Oral]), [CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM), COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral]), [SIBNASTATIN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral])	ICSR
EU-EC-100096007	11/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown -), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccine breakthrough infection (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000966703	10/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000968302	10/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aggression (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Agitation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Asthma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death), Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 81mg - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 180mg - n/a]), [CALCIUM CARBONATE, CALCIUM CARBONATE PH EUR] (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a])	ICSR
EU-EC-1000967479	10/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (n/a - Not Recovered/Not Resolved -), Confusional state (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Hives (n/a - Not Recovered/Not Resolved -), Lung infiltration (n/a - Not Recovered/Not Resolved -), Shock (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	[AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009671426	10/06/2021	Spontaneous	Not Healthcare Professional	European Economic Area	Not available	16-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000969379	10/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Chest pain (15d - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (15d - Fatal - Results in Death, Other Medically Important Condition), Reactivation (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	[ENBREL [ETANERCEPT]] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METHOTREXATE [METHOTREXATE]] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [INSULIN, INSULIN HUMAN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PREDNISONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-1000966029	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (55d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-100096626	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Balance disorder (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (n/a - Fatal - Results in Death), Gait disturbance (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Mobility decreased (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-100096680	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (2d - Fatal - Results in Death, Other Medically Important Condition), Decreased activity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspepsia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fluid retention (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Furunculoma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Generalised oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Left ventricular failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mesenteric vein thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Peripartum sweating (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Poor quality sleep (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Product dose omission issue (n/a - Unknown -), Septic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Supraventricular tachycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 81mg - Unknown]), [EMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown])	ICSR
EU-EC-1000966972	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Nausea (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ELIQUIS [APIXIBAN]] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [DIBUTYLMIN BIPHENYLAMINE, DIBUTYLMIN BIPHENYLAMINE DIHYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [MAGDARONE, AMODARONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown]), [MILCOPRINE, ALMOPRINE BESILATE, ALMOPRINE MALLEATE, ALMOPRINE MESLATE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [BENZAPRIL] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), [DIOXIN] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [FLUTICASON FURGATE, VILANTEROL, TRIFENATATE, FLUTICASON, VILANTEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [n/a - 500mg - Unknown]), [METOPROLOL, TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown])	ICSR

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Sex Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Involved Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-100089726	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (14 - Fatal - Results in Death, Other Medically Important Condition), General physical health deterioration (23 - Fatal - Results in Death), Influenza like illness (23 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100089701	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -), Pain (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100089151	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Abdominal pain upper (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Headache (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Illness (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR
EU-EC-100089323	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	Tumor (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation) Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hepatic failure (145 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (145 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SEQUELHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), AMFETAMINE SULFATE, DEXAMFETAMINE SULFATE, AMFETAMINE ASPARTATE, DEXAMFETAMINE SACCHARATE (C - Product used for unknown indication - n/a - [n/a - 30mg - Unknown]), [ESTRADIOL, ESTRADIOL HEMHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 75mg - Unknown]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 150mg - Unknown]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 75mg - Unknown]), [APIXIBAN [APIXIBAN]] (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), [CINACALCET [CINACALCET]] (C - Product used for unknown indication - n/a - [n/a - 30mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), [CALCIUM ACETATE] (C - Product used for unknown indication - n/a - [n/a - 400mg - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [HYDRAZINE] (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a]), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 3000mg - n/a]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), [BUDESONIDE, FORMOTEROL FLUMARATE DIHYDRATE, FORMOTEROL FLUMARATE, BUDESONIDE] (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), [BUSPIRONE, BUSPIRONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), [CYCLOBENZAPRINE, CYCLOBENZAPRINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	
EU-EC-100089490	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleuritic effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleuritic pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vascular graft thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894158	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dysuria (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Poor quality sleep (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Productive cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-100089304	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR
EU-EC-100089303	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Agnesia (214 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ascemia (214 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (214 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (214 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (214 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (214 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - Unknown)	Not reported	ICSR
EU-EC-10008942189	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	[CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [GLYCERYL TRINERATE] (C - Product used for unknown indication - n/a -), [INDAPAMIDE, INDAPAMIDE HEMHYDRATE] (C - n/a - n/a -), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Product used for unknown indication - n/a -), [LOSARTAN] (C - Product used for unknown indication - n/a - [n/a - 125mg - n/a]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIBHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CYCLOBENZAPRINE, CYCLOBENZAPRINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FLUTICASON PROPRIONATE, SALMETEROL XINAFOATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LISINAPRIL, LISINAPRIL ANHYDROUS, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BIF] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL, SUCONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NEMPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TITROPPIUM, TITROPPIUM BROMIDE, TITROPPIUM BROMIDE MONOHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	
EU-EC-1000894285	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894298	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (21 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894303	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894427	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Cardiac failure congestive (n/a - Fatal - Results in Death, Other Medically Important Condition), Condition aggravated (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR
EU-EC-1000894210	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Concussion (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fat (n/a - Fatal - Results in Death), Resuscitation (n/a - Fatal - Results in Death), Somnolence (n/a - Fatal - Results in Death), Syncope (n/a - Fatal - Results in Death, Other Medically Important Condition), Thrombosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Traumatic haemorrhage (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894293	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894372	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894380	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894542	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894808	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Asthma (376 - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (376 - Fatal - Results in Death), Pain (376 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000894857	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Shock (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894571	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894570	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894676	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894628	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894650	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894606	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Blood pressure decreased (n/a - Unknown -), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894608	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894660	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894663	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894684	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Chest pain (14 - Unknown - Life Threatening), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-1000894783	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Fatigue (865 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Syncope (865 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR

EU Local Number	EY Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group (as per reporter)	Patent Age Group (as per reporter)	Patent Sex	Patent Chn/ Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000894761	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (15d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac disorder (15d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Chest pain (15d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Coronary arterial stent insertion (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Decreased interest (15d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (15d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Headache (15d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation) Chills (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Hyperhidrosis (n/a - Fatal - Results in Death), Injection site erythema (n/a - Fatal - Results in Death), Injection site pruritus (n/a - Fatal - Results in Death), Injection site reaction (n/a - Fatal - Results in Death), Injection site swelling (n/a - Fatal - Results in Death), Pain (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	MEMANTINE (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), PENTOXIFYLLINE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000894777	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chills (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Hyperhidrosis (n/a - Fatal - Results in Death), Injection site erythema (n/a - Fatal - Results in Death), Injection site pruritus (n/a - Fatal - Results in Death), Injection site reaction (n/a - Fatal - Results in Death), Injection site swelling (n/a - Fatal - Results in Death), Pain (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	CSR
EU-EC-1000894849	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	CELECOXIB (S/CELECOXIB) (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), DEXAMETHASONE DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), JANUMET (METFORMIN HYDROCHLORIDE, EXAGLIFITIN, METFORMIN HYDROCHLORIDE, STAGLIFITIN PHOSPHATE, METFORMIN MONOHYDRATE) (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [ATENLOLOL, ATENLOLOL BP] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [CAFTOPRIL] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [DILTIAZEM] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [MACRODOL 3300] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [RISERODONATE MONOSODIUM, RISERODONATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown])	CSR
EU-EC-1000894870	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Lung disorder (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	CSR
EU-EC-1000894895	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Feeling abnormal (2d - Fatal - Results in Death), Macrovascular disorder (2d - Fatal - Results in Death), Neurospargitis (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000894929	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (77d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	BUMETANIDE (BUMETANIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ELIUS (APRAXAN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [COLCICALCIFEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000895053	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Respiratory distress (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	CSR
EU-EC-1000895010	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute kidney injury (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hyperkalemia (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripneal swelling (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	CSR
EU-EC-1000895071	07/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	SPRIKAV (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - n/a]), [NOT AVAILABLE] (S - Polypharmacy - Not applicable - [n/a - n/a - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE 20 MG - GASTRO-RESISTANT TABLET (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000895257	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	LEVEMIR (INSULIN DETEMIR) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FERROUS SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SEMFIPIROZOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [HYDRALAZINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [INSULIN ASPART] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [VALPROIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [RESERATAN (RESERATAN)] (C - n/a - n/a - [n/a - 300mg - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - Oral]), [ALLOPURINOL] (C - n/a - n/a - [n/a - 100mg - Oral]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - Oral]), [TRIMETAZIDINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - Oral]), [OZEMPIC (SEMAGLUTIDE)] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DIACETAMID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE] (C - Product used for unknown indication - n/a - [n/a - 3ml - Unknown]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TITROPPIUM BROMIDE] (C - Product used for unknown indication - n/a - [n/a - 18ug - n/a])	CSR
EU-EC-1000895701	07/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	SPRIKAV (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 0ml - Intramuscular])	VALPROIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), RESERATAN (RESERATAN) (C - n/a - n/a - [n/a - 300mg - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - Oral]), [ALLOPURINOL] (C - n/a - n/a - [n/a - 100mg - Oral]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - Oral]), [TRIMETAZIDINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - Oral]), [OZEMPIC (SEMAGLUTIDE)] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DIACETAMID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE] (C - Product used for unknown indication - n/a - [n/a - 3ml - Unknown]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TITROPPIUM BROMIDE] (C - Product used for unknown indication - n/a - [n/a - 18ug - n/a])	CSR
EU-EC-1000895289	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000895328	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Posture abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	LEVEMIR (INSULIN DETEMIR) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FERROUS SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SEMFIPIROZOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [HYDRALAZINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [INSULIN ASPART] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [VALPROIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [RESERATAN (RESERATAN)] (C - n/a - n/a - [n/a - 300mg - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - Oral]), [ALLOPURINOL] (C - n/a - n/a - [n/a - 100mg - Oral]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - Oral]), [TRIMETAZIDINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - Oral]), [OZEMPIC (SEMAGLUTIDE)] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DIACETAMID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE] (C - Product used for unknown indication - n/a - [n/a - 3ml - Unknown]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TITROPPIUM BROMIDE] (C - Product used for unknown indication - n/a - [n/a - 18ug - n/a])	CSR
EU-EC-1000895348	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown -), Influenza like illness (n/a - Unknown -), Pain in extremity (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	CSR
EU-EC-1000895506	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cerebral disorder (1d - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Lung disorder (1d - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal disorder (1d - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000895594	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown -), Dizziness (n/a - Unknown -), Feeling abnormal (n/a - Unknown -), Malnutrition (n/a - Unknown -), Pain (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	CSR
EU-EC-1000895820	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	CSR
EU-EC-1000896306	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Encephalopathy (4d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Generalised tonic-clonic seizure (4d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	INVEGA (PALIPERIDONE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), KEPPRA (LEVETIRACETAM) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DESVENLAFAXINE, DESVENLAFAXINE SUCCINATE MONOHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PHENOBARBITAL, PHENOBARBITAL SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a])	CSR
EU-EC-1000896047	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000896166	07/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Agnosia (n/a - Unknown -), Aphasia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown -), Disability (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Dysarthria (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Dyslexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Eating disorder (n/a - Not Recovered/Not Resolved - Disabling), Hand deformity (n/a - Unknown - Caused/Prolonged Hospitalisation), Hirsch (n/a - Unknown -), Impaired walking (n/a - Not Recovered/Not Resolved - Disabling), Movement disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscle weakness (n/a - Unknown -), Nausea (n/a - Unknown -), Peripneal swelling (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Peripneal swelling (n/a - Unknown -), Pyrexia (n/a - Unknown -), Speech disorder (n/a - Unknown -), Throat lesion (n/a - Unknown -), Vomiting (n/a - Unknown -), Weight decreased (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	CSR
EU-EC-1000896703	04/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	CSR
EU-EC-1000896212	04/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPRIKAV (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - n/a - n/a - [n/a - n/a - n/a])	CIRCADIN (MELATONIN) (C - n/a - n/a - [n/a - n/a - n/a]), KEPPRA (LEVETIRACETAM) (C - n/a - n/a - [n/a - n/a - n/a]), ALIMEMAZINE, ALIMEMAZINE TARTRATE (C - n/a - n/a - [n/a - n/a - n/a]), [LAMOTRIGINE] (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM SODIUM MACRODOL 3300, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACRODOL 3300] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000896246	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPRIKAV (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 0ml - n/a])	Not reported	CSR
EU-EC-1000896210	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (1d - Unknown -), Syncope (n/a - Fatal - Results in Death, Other Medically Important Condition)	SPRIKAV (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	Not reported	CSR
EU-EC-1000897273	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved -), Feeling abnormal (n/a - Not Recovered/Not Resolved -), Hot flash (n/a - Not Recovered/Not Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Unknown])	MELATONIN (MELATONIN) (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ALLOPURINOL] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), [ATENLOLOL, ATENLOLOL BP] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DEFALOXIN, DEFALOXIN MONOHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 250mg - Unknown]), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [VALSARTAN] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Unknown])	CSR
EU-EC-1000897045	03/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Essential hypertension (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hypocapnia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hypochloremia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vitamin B12 deficiency (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	CSR
EU-EC-1000898007	03/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac arrest (1d - Unknown - Life Threatening, Other			

EU Local Number	EY Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Reaction List (PT - Duration ? Outcome - Seriousness Criteria)	Suspecting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
EU-EC-100086251	01/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Female	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086253	01/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086250	01/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 65 Years	Not Specified	Female	Communication disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086257	01/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	Cardiac arrest (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086267	01/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	Chest pain (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Headache (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown), IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), POTASSIUM CHLORIDE (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown)	Not reported	CSR	
EU-EC-100086260	01/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	Cardiac arrest (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular - More in ICSR)	PAROXETINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a] - 20mg - n/a), TRAZODONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a] - 100mg - Unknown)	Not reported	CSR
EU-EC-100086271	01/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	Cardiac arrest (14 - Fatal - Results in Death, Other Medically Important Condition), Cyanosis (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (14 - Fatal - Results in Death, Other Medically Important Condition), Vomiting (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086260	01/06/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Female	Acute respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086301	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	SPRIKVA [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 5ml - Intramuscular)	Not reported	CSR	
EU-EC-100086347	31/05/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086475	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	Death (n/a - Fatal - Results in Death)	SPRIKVA [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a] - Intramuscular)	Not reported	CSR	
EU-EC-100086477	31/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening)	SPRIKVA [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086706	28/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	Cerebrovascular accident (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (134 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086772	28/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086786	28/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Food refusal (14 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular - More in ICSR)	Not reported	CSR	
EU-EC-100086840	28/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	Condition aggravated (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (14 - Fatal - Results in Death), Fatigue (14 - Fatal - Results in Death), Oedema peripheral (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086905	28/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086940	28/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086937	28/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Fatal - Results in Death), Tremor (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	AEROSOL SPTZNER [CAMPHOR, ESSENTIAL OILS NOS] (C - Product used for unknown indication - n/a -), IRON [IRON] (C - Product used for unknown indication - n/a - [n/a] - n/a), [BOTIN] (C - Product used for unknown indication - n/a - [n/a] - 5mg - n/a), [ESTROGEN NOS] (C - Product used for unknown indication - n/a -), HYDROXYZINE EMBONATE (C - Product used for unknown indication - n/a - [n/a] - 50mg - n/a), METHYLTESTOSTERONE (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), MINERALI NOS, VITAMINI NOS (C - n/a - n/a - [n/a] - 5mg - n/a), DIOXYCOONE, DIOXYCOONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a] - 5mg - n/a), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	Not reported	CSR
EU-EC-100086936	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	Abnormal behaviour (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Delusion (n/a - Fatal - Results in Death), Hallucination (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086945	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086948	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	Acute myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 2[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086958	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM (C - Product used for unknown indication - n/a - [n/a] - 500mg - Oral), [CHROMIUM PICOLINATE] (C - Product used for unknown indication - n/a - [n/a] - 400mg - Oral), [FISH OIL] (C - Product used for unknown indication - n/a - [n/a] - 1000mg - n/a), [MIFEPRISTONE] (C - Product used for unknown indication - n/a - [n/a] - 40mg - n/a), [LUBICERENONE] (C - Product used for unknown indication - n/a - [n/a] - 200mg - Oral), IRON [IRON] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [CALCIUM] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [ELECTROLIT] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [HYDROURONE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [METHOCARBAMOL] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [NICOTINE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	Not reported	CSR
EU-EC-100086958	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intensive care (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	Not reported	CSR
EU-EC-100086964	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Hypoxia (24 - Fatal - Results in Death, Life Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086965	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Female	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086963	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	Ashtenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	LANTUS [INSULIN GLARGINE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), SILDENAFIL CITRATE [SILDENAFIL CITRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [CATS CLAW] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [INSULIN ASPART] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [LEPFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPH] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [VITAMINI NOS] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	Not reported	CSR
EU-EC-100086967	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	Apnoea (14 - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[VITAMINI NOS] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Product used for unknown indication - n/a - [n/a] - 400mg - Unknown), ISOSORBIDE [CARBOHYDRATES NOS, FATS NOS, MINERALS NOS, PROTEINS NOS, VITAMINI NOS] (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown), METOPROLOL, SULCINATE (C - Product used for unknown indication - n/a - [n/a] - 100mg - Unknown), PARACETAMOL (C - Product used for unknown indication - n/a - [n/a] - 650mg - Unknown)	Not reported	CSR
EU-EC-100086974	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	CSR	
EU-EC-100086968	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086937	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086943	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	Brain herniation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Carotid artery occlusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Endotracheal intubation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086952	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	Apnoea (14 - Fatal - Results in Death, Other Medically Important Condition), Cardiac arrest (14 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Disorientation (14 - Fatal - Results in Death, Other Medically Important Condition), Feeling hot (n/a - Fatal - Results in Death, Other Medically Important Condition), Injection site pain (n/a - Fatal - Results in Death), Insomnia (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (14 - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	INSULIN GLARGINE [INSULIN GLARGINE] (C - Product used for unknown indication - n/a - [n/a] - 100U - Subcutaneous), [LUBICERENONE] (C - Product used for unknown indication - n/a - [n/a] - 200mg - Unknown), MUPROFEN (C - Product used for unknown indication - n/a - [n/a] - 400 - Topical), [BINASTATIN] (C - Product used for unknown indication - n/a - [n/a] - 20mg - n/a)	Not reported	CSR
EU-EC-100086940	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Male	Cardiac valve vegetation (n/a - Fatal - Results in Death, Other Medically Important Condition), Cognitive disorder (n/a - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Device related bacteremia (n/a - Fatal - Results in Death, Other Medically Important Condition), Etiology (n/a - Fatal - Results in Death, Other Medically Important Condition), Etiology (n/a - Fatal - Results in Death, Other Medically Important Condition), Hemal status changes (n/a - Fatal - Results in Death), Motor dysfunction (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR	
EU-EC-100086957	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Moaning (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular - More in ICSR)	HUMALOG [INSULIN LEPRIC] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), LUMIGAN [BIMATOPOST] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), RENVELA [SEVELAMER CARBONATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [ASCORBIC ACID, Biotin, CALCIUM PANTOTHENATE, CYANOCOBALAMIN, FOLIC ACID, NICOTINAMIDE, RIBOFLAVIN, THIAMINE, PYRIDOXINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [LACTULOSE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [MIDODRINE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	Not reported	CSR
EU-EC-100086972	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	CSR	
EU-EC-100086930	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	Atherosclerosis coronary artery (14 - Fatal - Results in Death), Cold sweat (n/a - Unknown -), Coronary artery occlusion (24 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Syncope (n/a - Unknown -), Parosmia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	MELATONIN [MELATONIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [GAMMA-AMINOBU TYRIC ACID] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [DITRIPTAN] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	Not reported	CSR
EU-EC-100086936	27/05/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 18 Years	Not Specified	Female	Death (14 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[NADOLOL] (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Unknown)	Not reported	CSR
EU-EC-100086938	27/05/												

EU Local Number	EV Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Chn Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Subject/Intervent Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
			Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Agitation (n/a - Unknown -), Anger (n/a - Unknown -), Cognitive disorder (n/a - Unknown -), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Diet refusal (n/a - Unknown -), Fat (n/a - Unknown -), Fluid intake reduced (n/a - Unknown -), Hallucination (n/a - Unknown - Other Medically Important Condition), Irritability (n/a - Unknown -), Neurological syndrome (n/a - Unknown -), Parosmia (n/a - Unknown -), Scrambling (n/a - Unknown -), Wheelchair user (n/a - Unknown -)	applicable - [n/a - 1DF] - Intramuscular]	[ANASTROZOLE] (C - Product used for unknown indication - n/a -), [ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a -), [ATORVASTATIN] (C - Product used for unknown indication - n/a -), [COLECALCIFEROL] (C - Product used for unknown indication - n/a -), [FISH OIL] (C - Product used for unknown indication - n/a - [n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a])	
EU-EC-1000801612	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000801817	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Product used for unknown indication - n/a -), [ALLOPURINOL] (C - Product used for unknown indication - n/a -), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - Product used for unknown indication - n/a -), [FUROSEMIDE] (C - Product used for unknown indication - n/a -)	CSR
EU-EC-1000802148	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000802272	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cerebral haemorrhage (2d - Fatal - Results in Death, Other Medically Important Condition), Cerebral ischaemia (5d - Fatal - Results in Death, Other Medically Important Condition), Cardiovascular accident (5d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Hemiplegia (2d - Fatal - Results in Death, Other Medically Important Condition), Pulsations (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000803218	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (4d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Autoimmune disorder (2d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood creatinine increased (n/a - Fatal - Results in Death), Blood disorder (4d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Blood pressure decreased (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Blood sodium decreased (2d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Blood urea increased (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Enzyme level increased (27d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Fluid retention (15d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hemoglobin decreased (6d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hemophagocytic lymphohistiocytosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Haemorrhage (27d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatic enzyme increased (23d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxemia (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Immune thrombocytopenia (2d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - Results in Death, Other Medically Important Condition), Increased tendency to bruise (57d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Joint swelling (30d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Mobility decreased (4d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (2d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (4d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Purpura swelling (30d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Platelet count decreased (5d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pneumonia (30d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (25d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - Results in Death), Sepsis (2d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (30d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Thrombotic thrombocytopenic purpura (n/a - Fatal - Results in Death, Other Medically Important Condition), Vaccination complication (57d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000803487	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthma (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000804618	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Abnormal X-ray (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lethargy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	LITEN + [ASCORBIC ACID, BETA-CAROTENE, COPPER, NICOTINAMIDE, SELENIUM, TOCOPHEROL, XANTOPYL, ZINC] (C - n/a - n/a - [n/a - 6mg - Unknown]), [ALPHA-TOCOPHEROL] (C - n/a - n/a - [n/a - 400IU] - Unknown), [CARVEDILOL] (C - Cardiology - n/a - [n/a - 6.5mg - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - Unknown]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - Unknown]), [GLIMEPIRIDE] (C - Diabetes mellitus - n/a - [n/a - 1mg - Oral]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - Hypertension - n/a - [n/a - 30mg - Oral]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - Oral]), [NAPROXEN] (C - n/a - n/a - [n/a - n/a - Unknown]), [NEMIPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 40mg - Unknown]), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - n/a - n/a - [n/a - 20mg - Unknown]), [PYRIDOXINE] (C - n/a - n/a - [n/a - n/a - Unknown]), [THIAMINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Unknown]), [THIAMINE HYDROCHLORIDE] (C - Cardiac failure chronic - n/a - [n/a - 10mg - Oral]), [VITAMIN B12] (C - n/a - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000805638	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000806298	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000806315	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea exertional (n/a - Not Recovers/Not Resolved - Caused/Prolonged Hospitalisation), Musculoskeletal chest pain (n/a - Not Recovers/Not Resolved - Caused/Prolonged Hospitalisation), Painful respiration (n/a - Not Recovers/Not Resolved - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Not Recovers/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	SILDENAFIL [SILDENAFIL] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), [TRIMEPRIDINE, ABACAVIR, LAMIVUDINE, DOLUTEGRAVIR] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [TORASEMIDE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown])	CSR
EU-EC-1000806418	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cardiac failure congestive (n/a - Unknown - Other Medically Important Condition), Condition aggravated (n/a - Unknown -), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Interchange of acidic products (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000806626	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	PRADAXA [DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a]), [DIOXIN] (C - Product used for unknown indication - n/a - [n/a - n/a]), [HYDROCHLOROQUINE] (C - Product used for unknown indication - n/a - [n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a])	CSR
EU-EC-1000806808	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Coronary artery disease (1d - Unknown - Other Medically Important Condition), Cough (1d - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000806974	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Abdominal wall haematoma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Arythmia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deep vein thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypovolaemic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Retroperitoneal haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus tachycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), [RANITIDINE, RANITIDINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a]), [VERAPAMIL, VERAPAMIL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 120mg - n/a])	CSR
EU-EC-1000807101	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000807076	27/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	No	COVID-19 (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Gastrointestinal haemorrhage (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspepsia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypovolaemic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lung infiltration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Metabolic acidosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Retroperitoneal haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus tachycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	FLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DILTIAZEM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DIPYRIMETHAMINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DIBAMPEPRIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CARIPRAZINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000807526	26/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000807545	26/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000807592	26/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Agusia (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Productive cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Unknown - Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000807630	26/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR
EU-EC-1000807640	26/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (0d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	SHINEVA [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 0mL - Intramuscular]	[ACEFI, SILDENAFIL ACETATE] (C - n/a - n/a - [n/a - 100mg - Oral]), [ALPRAZOLAM] (C - n/a - n/a - [n/a - n/a - Oral]), [AMLODIPINE BESILATE, PERINDOPRIL, ARGinine, AMLODIPINE, PERINDOPRIL] (C - n/a - n/a -), [ATORVASTATIN] (C - n/a - n/a -), [BENFOTAMINE] (C - n/a - n/a -), [CARVEDILOL] (C - n/a - n/a - [n/a - n/a - Oral]), [CLOSTAZOL] (C - n/a - n/a - [n/a - 100mg - Oral]), [FAMOTIDINE] (C - n/a - n/a - [n/a - n/a - Other]), [FRAMIDOL, HYDROCHLORIDE] (C - n/a - n/a -)	CSR
EU-EC-1000807627	26/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown)	Not reported	CSR
EU-EC-1000807678	26/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Unknown -), Aphasia (n/a - Unknown -), COVID-19 (n/a - Unknown -), Cough (n/a - Unknown -), Death (1d - Fatal - Results in Death), Distonia (n/a - Unknown - Other Medically Important Condition), Dysphagia (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Food refusal (n/a - Unknown -), Incontinent (n/a - Unknown -), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular]	Not reported	CSR
EU-EC-1000807989	26/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular]	Not reported	CSR

EU Local Number	EV Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Age Group	Sex	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspecting/Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form		
EU-EC-100873369	21/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Back pain (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fat (n/a - Unknown - Other Medically Important Condition), Fat (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-100873360	21/05/2021	Spontaneous	Not Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Athralgia (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Confusional state (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Neopharyngitis (n/a - Fatal - Results in Death), Platelet count decreased (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death), Urinary tract infection (n/a - Fatal - Results in Death)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-100873377	21/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (19d - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (19d - Unknown - Other Medically Important Condition), Fragile (19d - Unknown - Other Medically Important Condition), Hemiparesis (19d - Unknown - Life Threatening), Pallor (19d - Unknown - Other Medically Important Condition), Rectal haemorrhage (19d - Unknown - Life Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	ELIQUIS (APRAXAN) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), ENTRESTO (VALSARTAN, SACUBITRIL) (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), ACETYSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [LATANOPROST] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [DMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [VITAMIN D] (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID, ZINC, COPPER, RETINOL, ALPHA-TOCOPHEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DOLICALCIFEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DIOXIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MACRODOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Ophthalmic), [MELOXICAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PHENYTOIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SODIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SODIUM FLUORIDE, SODIUM MONOCLOROPHOSPHATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE)] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [TREBIA (INSULIN DESLORO)] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 900mg - n/a]), [MIRTAZAPINE] (C - Product used for unknown indication - n/a - [n/a - 15mg - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BISPHATATIN] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a - [n/a - 6mg - n/a])	
EU-EC-100873373	21/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dysphagia (n/a - Unknown - Other Medically Important Condition), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Pneumonia (2d - Unknown - Other Medically Important Condition), Unresponsive to stimuli (2d - Unknown - Other Medically Important Condition), Vomiting (2d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	VITAMIN D] (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID, ZINC, COPPER, RETINOL, ALPHA-TOCOPHEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DOLICALCIFEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DIOXIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MACRODOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Ophthalmic), [MELOXICAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PHENYTOIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SODIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SODIUM FLUORIDE, SODIUM MONOCLOROPHOSPHATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE)] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [TREBIA (INSULIN DESLORO)] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 900mg - n/a]), [MIRTAZAPINE] (C - Product used for unknown indication - n/a - [n/a - 15mg - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BISPHATATIN] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a - [n/a - 6mg - n/a])	
EU-EC-100873461	21/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Hypoglycaemia (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-100874105	21/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Hypertension (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008712070	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Adverse event (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-1008712075	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	NEBIVOLOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]), [ROSLIVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [80d - 10mg - Oral])	
EU-EC-1008712089	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008712091	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (2d4 - Unknown - Caused/Prolonged Hospitalisation), Fatigue (2d4 - Unknown - Caused/Prolonged Hospitalisation), Headache (2d4 - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (2d4 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[DOLOPHENAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE, BUPROFEN, BUPROFEN (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), [CICLOTIPIDE, Cimetidine HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown)	
EU-EC-1008712096	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Cardio-respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-1008712101	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Athralgia (n/a - Unknown -), Chills (n/a - Unknown -), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Headache (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Sleep disorder (n/a - Unknown -), Tinnitus (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	PIOGITAZONE (PIOGITAZONE, GLIMEPRIDE [PIOGITAZONE HYDROCHLORIDE, GLIMEPRIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), PIOGITAZONE (PIOGITAZONE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [ROSLIVASTATIN, ROSLIVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown)	
EU-EC-1008712102	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Thrombosis (n/a - Unknown -), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	INSULIN, INSULIN HUMAN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [LITHIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown)	
EU-EC-1008712104	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008712109	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Incomplete course of vaccination (1d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008712139	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008712141	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Product used for unknown indication - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008712732	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	ASPIRIN (ACETYSALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), ANOR (ELIQUIS, UMECLIDINIUM BROMIDE, VILANTEROL, UMECLIDINIUM BROMIDE, VILANTEROL, TRIFENATE, UMECLIDINIUM, VILANTEROL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [AMANTADINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [ATROPINE SULFATE PH. EUR., DIPHENXYLATE HYDROCHLORIDE BP, ATROPINE SULFATE, DIPHENXYLATE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [BETAMETHASONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [DICLOFENAC, DICLOFENAC POTASSIUM, DICLOFENAC SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [FLUTICASON PROPRIONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [GUAFENESIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [PRATROPILUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [LACTOBACILLUS ACIDOPHILUS, BIFIDOBACTERIUM BIFIDUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [MEMANTINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [NEOMYCIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown)	
EU-EC-1008712757	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008713839	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	Not reported	CSR
EU-EC-1008715722	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Injection site pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripartum swelling (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008717251	20/05/2021	Spontaneous	Not Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac disorder (2d - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fat (2d - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Stiff neck (2d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008717827	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008718567	20/05/2021	Spontaneous	Not Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008720199	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008720270	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008720716	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fat (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-1008721849	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Pallor (n/a - Unknown -), Peripartum swelling (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	Not reported	CSR
EU-EC-1008721932	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (1d - Unknown -), Pain (1d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008722099	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008722297	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	INSULIN LISPRO (INSULIN LISPRO) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	
EU-EC-1008722840	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Asthma (2d - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (2d - Unknown - Other Medically Important Condition), Hypertension (2d - Unknown - Other Medically Important Condition), Oedema (2d - Unknown - Other Medically Important Condition), Tachycardia (2d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	GABAPENTIN (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a])	
EU-EC-1008722882	20/05/2021	Spontaneous	Not Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Apnoea (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Hypokalaemia (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	SPRIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1008722892	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-							

EU Local Number	EV Safety Review Date	Report Type	Primary Source Qualification	Primary Country Regulatory Purpose	Literature Reference	Age Group	Sex	Patent Status	Patent No.	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Subjecting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-100072385	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Respiratory arrest (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	[AMIPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), [RIZATRIPATAN RIZATRIPATAN BENZOATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [UBIDECARENONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 81mg - n/a]), [ASCORBIC ACID] (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a]), [HYDRALAZINE] (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a]), [PRATAPROPRIL, SALBUTAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SODIUM BICARBONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PIANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a]), [ROSDIPH SEED OIL] (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a])	ICSR
EU-EC-100072461	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (3d - Unknown -), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-100072429	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-100072497	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-100072501	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Condition aggravated (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-100072506	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-100072567	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	CHIs (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Fat (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-100069263	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-100070209	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000701703	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Condition aggravated (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dementia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular - More in ICSR)	[ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 40mg - Oral]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Oral]), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a - 500mg - Unknown]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 400mg - Oral]), [FOSFOPRIL] (C - Product used for unknown indication - n/a - [n/a - 10mg - Oral]), [MEMANTINE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral])	ICSR
EU-EC-1000701933	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cardiac arrest (1d - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-100070200	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000702049	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	[LEVEMIR (INSULIN DETEMIR)] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ALFRAZOLAM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [INSULIN, INSULIN HUMAN] (C - Diabetes mellitus - n/a - [n/a - n/a - Subcutaneous]), [DIACETONE, DIACETONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BROMBLEN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-1000702388	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000702399	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cerebrovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dysarthria (n/a - Fatal - Results in Death), Gait inability (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000702658	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Headache (n/a - Unknown -), Hypertension (n/a - Unknown -), Hyposthenia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000703072	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000703410	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	[ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CHLORTALIDONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FENOFIBRATE, FENOFIBRATE MICRONISED] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [QUINAPRIL, QUINAPRIL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BUPROFEN, BUPROFEN, BUPROFEN SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 4mg - n/a])	ICSR
EU-EC-1000704457	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Body temperature increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Fat (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Rhabdomyolysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000692496	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	[CYANOCOBALAMIN, CYANOCOBALAMINE - BP] (C - Product used for unknown indication - Not applicable - [n/a - 1(D)] - Intramuscular)	ICSR
EU-EC-1000692776	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	[LORAZEPAM] (C - Product used for unknown indication - Not applicable - [n/a - 1mg - Oral]), [MACROGOL, 3350, PHTALOSIBUM CHLORIDE, SODIUM CARBONATE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, MACROGOL, 3350, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL, 3350, SODIUM SULPHATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, MACROGOL, 3350] (C - Product used for unknown indication - Not applicable - [n/a - 1(D)] - Intramuscular), [METHANAC ACID] (C - Product used for unknown indication - Not applicable - [n/a - 500mg - Oral]), [METANIZOLE SODIUM, METANIZOLE SODIUM MONOHYDRATE] (C - Product used for unknown indication - Not applicable - [n/a - 500mg - Oral]), [PARACETAMOL] (C - Product used for unknown indication - Not applicable - [n/a - 1000mg - Oral]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [INSULIN, INSULIN HUMAN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL, METOPROLOL, TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-1000695547	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Critical illness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death), Food intolerance (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Terminal date (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unknown event (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000693964	17/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000692574	17/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Bradycardia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown -), Fat (n/a - Unknown -), Malaise (n/a - Unknown -), Myriadia (n/a - Unknown -), Myocardial necrosis marker increased (n/a - Unknown - Other Medically Important Condition), Pulse absent (n/a - Unknown -), Pupils fixed (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	[BUPROFEN, BUPROFEN, BUPROFEN SODIUM] (C - Product used for unknown indication - n/a - [n/a - 200mg - n/a]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 81mg - n/a]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a - 1(D)] - Oral)	ICSR
EU-EC-1000691274	17/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000694630	15/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000694419	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000694525	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000694544	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Headache (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000694596	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000694674	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000694676	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000694973	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute kidney injury (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Urinary tract infection (24d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000694970	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000692464	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000692680	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000692692	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	[ALLOPURINOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BUPROPION HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL, METOPROLOL, TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-1000693538	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000693552	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	[SHINGRIX (RECOMBINANT VACCINIA ZOSTER VIRUS GLYCOPROTEIN E, STIMULON, MONOPHOSPHORYL LIPID)] (C - Product used for unknown indication - Not applicable - [n/a - 1(D)] - Intramuscular)	ICSR
EU-EC-1000693571	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)			

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
EU-EC-1000865361	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	Body temperature increased (1d - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Sepsis (1d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[DABEPENTIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), MONTELUKAST MONTELUKAST SODIUM (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), SALBUTAMOL SULFATE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	CSR
EU-EC-1000865368	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000865384	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000865389	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory arrest (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000865428	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000865437	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[DAPTOMYCIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - Intravenous (not otherwise specified))	CSR
EU-EC-1000865476	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000861409	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	Death (1d - Fatal - Results in Death), Convulsion (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000864353	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death), Headache (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown -), Nausea (n/a - Unknown -), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	CSR
EU-EC-1000866156	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Blood pressure increased (10d - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Hyperhidrosis (10d - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (10d - Not Recovered/Not Resolved - Other Medically Important Condition), Tachypnoea (10d - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	APIXABAN (APIXABAN) (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), CLOPIDOGREL (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [BISACODYL, DUCOSATE SODIUM, SODIUM PICOGLICOLATE MONOHYDRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [DUCOSATE SODIUM, CASSIA] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [FRAXETERONE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [METOPROLOL SUCCINATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [TAMSOLOLIN, TAMSOLOLIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	CSR
EU-EC-1000862728	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (0d - Fatal - Results in Death), Seizure (n/a - Unknown - Other Medically Important Condition)	SPRIVEX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000862706	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Chest pain (0d - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Dizziness (20d - Unknown - Caused/Prolonged Hospitalisation), Fatigue (20d - Unknown - Caused/Prolonged Hospitalisation), Feeling abnormal (20d - Unknown - Caused/Prolonged Hospitalisation), Malaise (20d - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[AMLODIPINE BESILATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a] - 25mg - Unknown)	CSR
EU-EC-1000863896	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Somnolence (20d - Unknown - Caused/Prolonged Hospitalisation) Body temperature increased (n/a - Unknown -), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[FERROUS SULFATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	CSR
EU-EC-1000863825	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular - More in ICSR)	Not reported	CSR
EU-EC-1000863072	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	SPRIVEX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[ELIUS (APIXABAN)] (C - Product used for unknown indication - Not applicable - [n/a] - 5mg - Oral), [PREGABALIN (PREGABALIN)] (C - Product used for unknown indication - n/a - [n/a] - 75mg - Oral), [AMODARONE, AMODARONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - 200mg - Oral), [BISOPROLOL] (C - Product used for unknown indication - Not applicable - [n/a] - 5mg - Oral), [FENTANYL] (C - Product used for unknown indication - Not applicable - [n/a] - n/a - Transdermal), [TORSEMIDE] (C - Product used for unknown indication - Not applicable - [n/a] - 10mg - Oral)	CSR
EU-EC-1000864917	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Constipation (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Patechnee (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[ELIUS (APIXABAN)] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [ENTRESTO (VALSARTAN, SACUBITRIL)] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [ACEYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [CYANOCOBALAMIN, VITAMIN B12] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [DIOXIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [DONEPEZIL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [GLUCOSE, GLUCOSE MONOHYDRATE, GLUCOSE, ANHYDROUS] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [INSULIN ASPART] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [LINAGLIPTIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [LORAZEPAM] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [NOMIFLAMATE, TAMSOLOLIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [SPIRONOLACTONE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [TEMAZEPAM] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [VITAMIN D] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000864803	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	GI sweet (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Confusional state (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Fall (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Head injury (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Painless electrical activity (1d - Fatal - Results in Death), Sight abnormal (1d - Not Recovered/Not Resolved -), Ventricular fibrillation (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000864263	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	Blood glucose increased (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Dyspnoea (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Unresponsive to stimuli (1d - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[ACEYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [AMLODIPINE, AMLODIPINE BESILATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [DABEPENTIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [HYDROXYZINE DIHYDROCHLORIDE, HYDROXYZINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [METFORMIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000861719	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Chest pain (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	Not reported	CSR
EU-EC-1000861704	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Asthma (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular - More in ICSR)	[ENTRESTO (VALSARTAN, SACUBITRIL)] (C - Product used for unknown indication - n/a - [n/a] - 25mg - n/a), [ANJAVIA (SITAGLIPTIN, SITAGLIPTIN PHOSPHATE, SITAGLIPTIN PHOSPHATE MONOHYDRATE)] (C - Product used for unknown indication - n/a - [n/a] - 50mg - n/a), [XARELTO (RIVAROXABAN)] (C - Product used for unknown indication - n/a - [n/a] - 2.5mg - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a] - 6.25mg - n/a), [FAMOTIDINE, FAMOTIDINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE] (C - Product used for unknown indication - n/a - [n/a] - 40mg - n/a), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - n/a), [GLUCOSE] (C - Product used for unknown indication - n/a - [n/a] - 5mg - n/a), [THIAMAZOLE] (C - Product used for unknown indication - n/a - [n/a] - 5mg - n/a)	CSR
EU-EC-1000861840	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[ACEYLSALICYLIC ACID] (C - Product used for unknown indication - Unknown - [n/a] - n/a - Unknown), [AMODARONE, AMODARONE HYDROCHLORIDE] (C - Product used for unknown indication - Unknown - [n/a] - 200mg - Unknown), [ATORVASTATIN] (C - Product used for unknown indication - Unknown - [n/a] - 80mg - Unknown), [FAMOTIDINE] (C - Product used for unknown indication - Unknown - [n/a] - 20mg - Unknown), [FUROSEMIDE] (C - Product used for unknown indication - Unknown - [n/a] - 40mg - Unknown), [SABAPENTIN] (C - Product used for unknown indication - Unknown - [n/a] - 300mg - Unknown), [LINSINAPRIL, LINSINAPRIL DIHYDRATE] (C - Product used for unknown indication - Unknown - [n/a] - 2.5mg - Unknown), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Product used for unknown indication - Unknown - [n/a] - 1000mg - Unknown), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - Unknown - [n/a] - 25mg - Unknown), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - Unknown - [n/a] - n/a - Unknown), [SPIRONOLACTONE] (C - Product used for unknown indication - Unknown - [n/a] - 25mg - Unknown), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Product used for unknown indication - Unknown - [n/a] - 50mg - Unknown)	CSR
EU-EC-1000861904	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Cognitive disorder (n/a - Unknown -), Death (1d - Fatal - Results in Death), General physical health deterioration (n/a - Unknown -), Hallucination (n/a - Unknown -), Headache (n/a - Unknown -), Mongonitis (n/a - Unknown -), Neck pain (n/a - Unknown -), Somnolence (n/a - Unknown -), Swelling (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[DUTASTERIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [TAMSOLOLIN, TAMSOLOLIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	CSR
EU-EC-1000861970	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intracranial aneurysm (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Life support (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular - More in ICSR)	[MELOXICAM] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000861908	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular - More in ICSR)	Not reported	CSR
EU-EC-1000862040	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Feeling abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[INSULIN, INSULIN HUMAN] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000862212	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	Back pain (n/a - Unknown -), Death (1d - Fatal - Results in Death), Influenza like illness (n/a - Unknown -), Pain in extremity (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[HUMIRA (ADALIMUMAB)] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [IRON (IRON)] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [PREDNISON] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000862366	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Cough (1d - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dizziness (1d - Unknown - Other Medically Important Condition), Muscular weakness (1d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - n/a)	[THIAMINE HYDROCHLORIDE, RETINOL] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [FLUTICASON, FLUTICASON, VILANTEROL, TRIFENATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [SALBUTAMOL, SALBUTAMOL, MICROZONED, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000862450	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Peripheral oedema (1d - Unknown -), Pulse absent (1d - Unknown -), Respiratory arrest (1d - Unknown -), Thrombosis (1d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [DABEPENTIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000862442	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Ventilation failure (n/a - Fatal - Results in Death)	SPRIVEX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a] - n/a - n/a)	[XELANZO (TOPOTECAN, TOPOTECAN CITRATE)] (C - n/a - Unknown - [n/a] - n/a - n/a), [ALLOPURINOL] (C - n/a - Unknown - [n/a] - n/a - n/a), [METHYLPREDNISOLONE] (C - n/a - Unknown - [n/a] - n/a - n/a)	CSR
EU-EC-1000862674	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Abdominal mass (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	[LINSINAPRIL, LINSINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	CSR
EU-EC-1000862890	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	SPRIVEX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - n/a)	[BETAMETHASONE, BETAMETHASONE DIPROPIONATE, SALICYLIC ACID, BETAMETHASONE DIPROPIONATE, SALSALATE, BETAMETHASONE, SALICYLIC ACID] (C - Skin disorder - n/a - [n/a] - 1[Df] - Cutaneous), [DISULFIRAM] (C - Alcohol problem - n/a - [n/a] - n/a - Oral), [SULFAMETHOXAZOLE] (C - Cystitis - n/a - [n/a] - 1000mg - Oral)	CSR
EU-EC-1000863082	12/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	SPRIVEX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a] - n/a - n/a)	[KENDRINIC, FERUSULFATE] (C - Sore - n/a - [21y - n/a - n/a]), [CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Myocardial ischaemia - n/a - [21y - n/a - n/a]), [LANTUS (INSULIN GLARGINE)] (C - Insulin-requiring type 2 diabetes mellitus - n/a - [21y - n/a - n/a]), [LINAGLIPTIN, LINAGLIPTIN] (C - Insulin-requiring type 2 diabetes mellitus - n/a - [21y - n/a - n/a]), [NOVORAPD (INSULIN ASPART)] (C - Insulin-requiring type 2 diabetes mellitus - n/a - [21y - n/a - n/a]), [ATENOLOL, ATENOLOL BP] (C - Myocardial ischaemia - n/a - [21y - n/a - n/a]), [ATORVASTATIN] (C - Hyper	

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
			Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Hepatic failure (16 - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (73 - Unknown -), Renal failure (16 - Recovered/Resolved - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (16 - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), Hospitalisation (235 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		
EU-EC-100893303	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Hospitalisation (235 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100893143	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100893895	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100894915	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Hospitalisation (284 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100894983	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100894962	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthma (16 - Unknown - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (16 - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fat (16 - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (16 - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (16 - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)	ARIPRAZOLE (ARIPRAZOLE) (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), ELIGIUS (ARIPRAZOLE) (C - Product used for unknown indication - n/a - [16] - [1DF] - Unknown), AMLODIPINE AMLODIPINE BESILATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), BUSPIRONE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), DELANIPRAZOLE (DELANIPRAZOLE) (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), DIZAPAN (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), FLUTICASON (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), FLUTICASON (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), FOLIC ACID (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), SABAPENTIN (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), HYDRAZINE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), LINACLOTIDE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), MONTELUKAST, MONTELUKAST SODIUM (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), PROPANOLOL, PROPANOLOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), ROBUVASTATIN, ROBUVASTATIN CALCIUM (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), TOPIRAMATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), TRAZODONE, TRAZODONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), VENAFAXINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown)	
EU-EC-100894761	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Balance disorder (16 - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), General physical health deterioration (16 - Unknown - Caused/Prolonged Hospitalisation), Memory impairment (16 - Unknown - Caused/Prolonged Hospitalisation), Neurological symptom (16 - Unknown - Caused/Prolonged Hospitalisation), Syncope (16 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100895255	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Nausea (16 - Unknown -), Unresponsive to stimuli (16 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100895312	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abdominal discomfort (16 - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100895313	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100895946	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chest pain (16 - Unknown -), Cough (68 - Unknown -), Death (14 - Fatal - Results in Death), Dyspnoea (68 - Unknown -), Headache (68 - Unknown -), Oropharyngeal pain (68 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)	BACLOFEN (C - Product used for unknown indication - n/a - [16] - n/a - n/a), CARBIDOPA, LEVODOPA, LEVODOPA, CARBIDOPA MONOHYDRATE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), CYANOCOBALAMIN (C - Product used for unknown indication - n/a - [16] - n/a - n/a), FUROSEMIDE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), SABAPENTIN (C - Product used for unknown indication - n/a - [16] - n/a - n/a), LACTULOSE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), PARACETAMOL (C - Product used for unknown indication - n/a - [16] - n/a - n/a), RIFAXIMIN (C - Product used for unknown indication - n/a - [16] - n/a - n/a), SPRONOLACTONE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), AMOXICILIN, AMOXICILIN HYDROCHLORIDE, AMOXICILIN TRIHYDRATE, AMOXICILIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILIN CLAVULANIC ACID, AMOXICILIN, POTASSIUM CLAVULANATE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), ATROPINE SULFATE, DIPHENOXILATE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), BACLOFEN (C - Product used for unknown indication - n/a - [16] - n/a - n/a), DEXTRORHOPHAN HYDROBROMIDE, GUAFENESIN (C - Product used for unknown indication - n/a - [16] - n/a - n/a), DIZAPAN (C - Product used for unknown indication - n/a - [16] - n/a - n/a), DICLOFENAC HYDROCHLORIDE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), DOXUSATE SODIUM (C - Product used for unknown indication - n/a - [16] - n/a - n/a), FINASTERIDE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), LINACLOTIDE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), METHANEMINE MANDELATE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), DIPLOM TINCTURE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), QUETIAPINE, QUETIAPINE FUMARATE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), SALBUTAMOL, SALBUTAMOL SULFATE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), TITROPOLIUM, TITROPOLIUM BROMIDE, TITROPOLIUM BROMIDE MONOHYDRATE (C - Product used for unknown indication - n/a - [16] - n/a - n/a)	
EU-EC-100895926	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Acute respiratory failure (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Cough (14 - Not Recovered/Not Resolved - Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (14 - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100895943	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (23 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Respiratory distress (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100895968	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100896263	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100896596	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100896611	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Alkaline phosphatase (16 - Unknown - Caused/Prolonged Hospitalisation), Anticoagulant block (16 - Unknown - Caused/Prolonged Hospitalisation), Blood calcium decreased (16 - Unknown - Caused/Prolonged Hospitalisation), Blood sodium decreased (16 - Unknown - Caused/Prolonged Hospitalisation), C-reactive protein increased (16 - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (16 - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), Hemoglobin decreased (16 - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (16 - Unknown - Caused/Prolonged Hospitalisation), Supraventricular extrasystoles (16 - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (16 - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)	ACEYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), AMLODIPINE, AMLODIPINE BESILATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), ATORVASTATIN (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), SABAPENTIN (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), PREDNISONE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), VITAMIN D3 (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), ATORVASTATIN (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown)	
EU-EC-100896902	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100896949	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Incomplete course of vaccination (16 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-100896979	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Respiratory arrest (16 - Fatal - Results in Death), Respiratory disorder (16 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)	ACEYLSALICYLIC ACID (C - Product used for unknown indication - Not applicable - [16] - [1DF] - Unknown), AMLODIPINE BESILATE (C - Product used for unknown indication - Not applicable - [16] - [1DF] - Unknown), DOXOSATE SODIUM (C - Product used for unknown indication - Not applicable - [16] - [1DF] - Unknown), NAPROXEN, NAPROXEN SODIUM (C - Product used for unknown indication - Not applicable - [16] - [1DF] - Unknown), VITAMINS NOS3 (C - Product used for unknown indication - Not applicable - [16] - [1DF] - Unknown)	
EU-EC-1008969150	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chest pain (16 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Injection site pain (16 - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-1008970247	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Decreased appetite (16 - Unknown - Other Medically Important Condition), Fat (16 - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)	FUROSEMIDE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), SIBASTATIN (C - Product used for unknown indication - n/a - [16] - n/a - Unknown)	
EU-EC-1008970313	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Syncope (16 - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-1008970383	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Bradycardia (26 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (24 - Unknown - Caused/Prolonged Hospitalisation), Fat (24 - Unknown - Caused/Prolonged Hospitalisation), Fatigue (24 - Unknown - Caused/Prolonged Hospitalisation), Hypotension (24 - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (24 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lactic acidosis (24 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus node dysfunction (24 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (24 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)	ACEYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), ALLIUM SATIVUM (BULB) (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), ASCORBIC ACID, ZINC, COPPER, RETINOL, ALPHA-TOCOPHEROL (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), LEVOTHYRONE, LEVOTHYRONE SODIUM (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), MINERALS NOS3, VITAMINS NOS3 (C - Product used for unknown indication - n/a - [16] - n/a - Unknown)	
EU-EC-10089701915	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Brain injury (16 - Unknown - Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (16 - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (16 - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (16 - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (16 - Unknown - Caused/Prolonged Hospitalisation), Pulmonary embolism (16 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Right ventricular dilation (16 - Unknown - Caused/Prolonged Hospitalisation), Right ventricular failure (16 - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-10089692919	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)	PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - Product used for unknown indication - n/a - [16] - [1DF] - Unknown), LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), MAGNESIUM OXIDE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), MIRTAZAPINE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), SERTRALINE, SERTRALINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), SOTALOL, SOTALOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), TRAMADOL, TRAMADOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown)	
EU-EC-10089692975	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)	VITAMINS NOS3 (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), CLOROPERIDOL, CLOROPERIDOL, CLOROPERIDOL BESILATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), MYOINOSITOL MONOETHYL, MYOINOSITOL MONOETHYL (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), AMLODIPINE BESILATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), FAMOTIDINE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), HYDRAZINE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), VALPROATE SODIUM (C - Product used for unknown indication - n/a - [16] - n/a - Unknown)	
EU-EC-10089692857	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Peripheral embolism (16 - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-10089692861	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-10089693027	10/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Myocardial infarction (14 - Fatal - Results in Death), Respiratory arrest (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)	IBUPROFEN (IBUPROFEN, IBUPROFEN SODIUM) (C - Product used for unknown indication - n/a - [16] - n/a - n/a), ALLOPURINOL (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), DOLCHICONE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), DICLOFENAC, DICLOFENAC POTASSIUM, DICLOFENAC SODIUM (C - Product used for unknown indication - n/a - [16] - n/a - n/a), INDOMETHACIN SODIUM TRISULFATE (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), MONTELUKAST, MONTELUKAST SODIUM (C - Product used for unknown indication - n/a - [16] - n/a - Unknown), SALBUTAMOL, SALBUTAMOL SULFATE (C - Product used for unknown indication - n/a - [16] - n/a - n/a), VITAMIN D3 (C - Product used for unknown indication - n/a - [16] - n/a - n/a)	
EU-EC-10089574928	08/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Vaccination site pain (16 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)		ICSR
EU-EC-10089577065	08/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardio-respiratory arrest (16 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [16] - [1DF] - Unknown)	PROCORALAN (VABRADINE HYDROCHLORIDE) (C - n/a - n/a - [16] - n/a - n/a	

EU Local Number	EV Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Qualification	Literature Reference	Patient Age Group	Patient Sex	Patient Race	Patient Ethnicity	Reaction List (Duration / Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form	
										Death (14 - Fatal - Results in Death)		(ACETYLSALICYLIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]), (ALLOPURINOL) (C - n/a - n/a - [n/a - n/a - n/a]), (AMLODIPINE BESILATE, FERROUS HYDROXYDE) (C - n/a - n/a - [n/a - n/a - n/a]), (CARVEDILOL) (C - n/a - n/a - [n/a - n/a - n/a]), (METFORMIN HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (ROSUVASTATIN, ROSUVASTATIN CALCIUM) (C - n/a - n/a - [n/a - 10mg - n/a]), (DOPING) (C - n/a - n/a - [n/a - n/a - n/a]), (DOLAZON, COLAZON MESILATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (BISFEDON) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR	
EU-EC-1000857079	08/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Hypophagia (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Somnolence (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-10008564812	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (14 - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Hypotonia (n/a - Fatal - Results in Death), Respiratory rate increased (n/a - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000856530	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Unknown - More in CSR)	Not reported	CSR	
EU-EC-1000856508	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular - More in CSR)	Not reported	CSR	
EU-EC-1000856528	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular - More in CSR)	Not reported	CSR	
EU-EC-1000856597	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (28 - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Hyperhidrosis (28 - Unknown - Other Medically Important Condition), Nausea (28 - Unknown - Other Medically Important Condition), Pyrexia (28 - Unknown - Other Medically Important Condition), Seizure (28 - Unknown - Other Medically Important Condition), Vomiting (28 - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000856701	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (21 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000856727	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Unknown - [n/a - 100] - Intramuscular)	LYRICA (PREGABALIN) (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown]), (ALPRAZOLAM) (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), (CITALOPRAM HYDROBROMIDE) (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), (DAYSODONE, DAYSODONE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - 15mg - Unknown])	CSR	
EU-EC-1000856751	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Death (14 - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Lethargy (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular - More in CSR)	INSULIN, INSULIN HUMANE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR	
EU-EC-1000856795	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular - More in CSR)	Not reported	CSR	
EU-EC-1000856804	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000856807	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000856813	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000856819	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000857151	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	DEXAMETHASONE (DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR	
EU-EC-1000857347	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	(DIOXIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (METOPROLOL, METOPROLOL TARTRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (DMEPRAZOLE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR	
EU-EC-100085189	06/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Not Specified	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	(TITROPPIUM, TITROPPIUM BROMIDE, TITROPPIUM BROMIDE MONOHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR	
EU-EC-1000856139	06/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac failure (21 - Fatal - Results in Death), Death (21 - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000856130	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	XARELTO (RIVAROXABAN) (C - Clozapine) (n/a - [n/a - n/a - Unknown])	CSR	
EU-EC-1000856645	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000856728	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular])	PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (TRAVOPROST) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ACETYLSALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (BUMETANIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (FDIC ACID, FERROUS SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (HYDROXYMELLOSE, GLYCEROL, MACROGOL 400, POLYVINYL ALCOHOL, PROPYLENE GLYCOL, VASELINE, LIQUID PARAFFIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (TAMBULOSON, TAMBULOSON HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (VITAMINS NOS) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000856808	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	CSR	
EU-EC-1000856976	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000856985	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Pulseless electrical activity (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	INSULIN ASPART (INSULIN ASPART) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (BISOPROLOL, BISMARTAN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - Product used for unknown indication - n/a - [n/a - 18g - Unknown])	CSR	
EU-EC-1000856971	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Unknown)	Not reported	CSR	
EU-EC-1000856431	06/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Behaviour disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Constipation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fat (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hyperosmia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular - More in CSR)	CLOPIDOGREL (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR	
EU-EC-1000854423	05/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Original pain (n/a - Unknown - Life Threatening), Hypophagia (n/a - Unknown - Life Threatening), Loss of personal independence in daily activities (n/a - Unknown - Life Threatening), Oral infection (n/a - Unknown - Life Threatening), Swelling face (n/a - Unknown - Life Threatening), Toothache (n/a - Unknown - Life Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	(ACETYLSALICYLIC ACID, ASPIRIN BP) (C - Product used for unknown indication - n/a - [n/a - 81mg - n/a]), (CRANBERRY) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (DOXYCYCLINE, DOXYCYCLINE HYDRATE, DOXYCYCLINE MONOHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (ESTROGENS CONJUGATED, ESTRONE SODIUM SULFATE, EQUILIN SULFATE SODIUM) (C - Product used for unknown indication - n/a - [n/a - 625mg - n/a]), (HYDRAZINE) (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a]), (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - Product used for unknown indication - n/a - [n/a - 112mg - n/a]), (LISINAPRIL, LISINAPRIL DIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), (NITROFURANTON) (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), (VITAMINS NOS) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR	
EU-EC-100085252	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Amyloma (n/a - Fatal - Results in Death), Death (14 - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000852530	04/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000852526	04/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Fatigue (n/a - Unknown -), Perioral swelling (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000852478	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Cough (n/a - Unknown -), Death (14 - Fatal - Results in Death), Nasopharyngitis (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Productive cough (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular - More in CSR)	PROTEIN (PROTEIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ACETYLSALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (CLONAZEPAM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (DONEPEZIL, DONEPEZIL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), (TEMAZEPAM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (TRAMADOL, TRAMADOL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR	
EU-EC-1000852561	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (21 - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	CSR	
EU-EC-1000852565	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (21 - Fatal - Results in Death, Life Threatening)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [21g - 5mg - Intramuscular])	(WARFARIN, WARFARIN SODIUM) (C - Anticoagulant therapy - Dose not changed -)	CSR	
EU-EC-1000852608	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Muddy decreased (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a -)	CSR	
EU-EC-1000852638	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (28 - Fatal - Results in Death), Vaccination site pain (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000852823	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	(ACETYLSALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - 81mg - Unknown]), (ATORVASTATIN) (C - Product used for unknown indication - n/a - [n/a - 80mg - Unknown]), (SILICISAMINE SULFATE, CHONDROITIN SULFATE SODIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (METOPROLOL, METOPROLOL TARTRATE) (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), (RAMPRIL) (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), (VITAMINS NOS) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	CSR
EU-EC-1000852916	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Myocardial infarction (14 - Unknown - Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	(ACETYLSALICYLIC ACID, ASPIRIN BP) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (METOPROLOL, METOPROLOL TARTRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (OLMESARTAN, OLMESARTAN MEDOXOMIL) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (BISFEDON) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (BIFEMAR) (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), (LOSARTAN, LOSARTAN POTASSIUM) (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a])	CSR	
EU-EC-1000853242	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Ataxic fibrillation (18) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Atrial flutter (18) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Cardiomegaly (18) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Death (14 - Fatal - Results in Death), Dyspnoea (18) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Dyspnoea exertional (18) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Pleural effusion (18) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Pulmonary congestion (18) - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	ENTRESTO (SALSARTAN, SACUBITRIL) (C - Cardiac failure - Dose not changed - [n/a - 200mg - Oral]), (ACETYLSALICYLIC ACID) (C - Acute myocardial infarction - Dose not changed - [n/a - 100mg - Oral]), (ATORVASTATIN, EZITIMIBE) (C - Hypercholesterolemia - Dose not changed - [n/a - 10mg - Oral]), (CARVEDILOL) (C - Cardiac failure - Dose not changed - [n/a - 25mg - Oral])	CSR	
EU-EC-1000851808	03/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (14 - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 100] - Intramuscular)	Not reported	CSR	
EU-EC-1000851910	03/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form	
			Healthcare Professional	Non European Economic Area	Not available	More than 15 Years	Not Specified	Male	No	Fatigue (n/a - Fatal - Results in Death)	VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	IRON (IRON) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); LYRICA (PREGABALIN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); ACEFYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); ALLIUM SATIVUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); ALPHAZOLAM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); AMLODIPINE, AMLODIPINE BESILATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); ASCORBIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); ATROPINE SULFATE Ph. Eur., DIPHENHYLATE HYDROCHLORIDE BP, ATROPINE SULFATE, DIPHENHYLATE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); CARVEDILOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); COLCALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); CYCLOSPORINE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); DOCSALATE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); FISH OIL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); INSULIN, INSULIN HUMAN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); EMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); SUCRALFATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); TEMAZEPAM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])		
EU-EC-1000852026	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 15 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Hypertension (n/a - Unknown -), Respiratory disorder (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)		ICSR	
EU-EC-1000852078	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal impairment (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	BUDESONIDE, FORMOTEROL, FLUMARATE DIHYDRATE, FORMOTEROL, FLUMARATE, BUDESONIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); CAMPOR, LEVOMENTHOL PH. EUR., EUCALYPTUS OIL PH. EUR., TURPENTINE OIL PH. EUR., CAMPOR, TURPENTINE OIL, LEVOMENTHOL PH. EUR., EUCALYPTUS OIL PH. EUR., LEVOMENTHOL, CAMPOR, EUCALYPTUS OIL, THYMOL, TURPENTINE ESSENTIAL OIL, LEVOMENTHOL, CAMPOR, EUCALYPTUS OIL, THYMOL, TURPENTINE OIL, LEVOMENTHOL, CAMPOR, RACEMIC, EUCALYPTUS OIL, THYMOL, TURPENTINE OIL, LEVOMENTHOL, CAMPOR, TURPENTINE OIL, EUCALYPTUS OIL PH. EUR., MENTHOL, CAMPOR, EUCALYPTUS OIL, THYMOL, TURPENTINE MENTHOL, CAMPOR, EUCALYPTUS OIL, THYMOL, TURPENTINE ESSENTIAL OIL, MENTHOL, CAMPOR, EUCALYPTUS OIL, THYMOL, TURPENTINE OIL, MENTHOL, CAMPOR, EUCALYPTUS OIL, THYMOL, TURPENTINE ESSENTIAL OIL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); DEXTRAMETHORPHAN HYDROBROMIDE, PHENYLEPHRINE HYDROCHLORIDE, GUAFENESIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); FLUTICASON, FLUTICASONIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])		ICSR
EU-EC-1000852037	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Influenza (n/a - Unknown - Caused/Prolonged Hospitalisation), Myasthenia gravis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown)	Not reported	ICSR	
EU-EC-1000852075	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (254 - Fatal - Results in Death), Condition aggravated (254 - Fatal - Results in Death), Death (254 - Fatal - Results in Death), Decreased appetite (254 - Fatal - Results in Death), Fatigue (254 - Fatal - Results in Death), Gastric disorder (254 - Fatal - Results in Death), Malaria (254 - Fatal - Results in Death), Pain (254 - Fatal - Results in Death), Pyrexia (254 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown)	ATORVASTATIN (C - Product used for unknown indication - n/a - [n/a - 1DF] - n/a); CARVEDILOL (C - Product used for unknown indication - n/a - [n/a - 1DF] - n/a); FURUSEMIDE, FURUSEMIDE SODIUM (C - Product used for unknown indication - n/a - [n/a - 1DF] - n/a); LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - 1DF] - n/a)		ICSR
EU-EC-1000852077	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular - More in ICSR)	DULOXETINE [DULOXETINE, DULOXETINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); HUMAN NORMAL IMMUNOGLOBULIN [HUMAN NORMAL IMMUNOGLOBULIN] (C - Product used for unknown indication - n/a - [n/a - 10% - Unknown]); AZELASTINE, AZELASTINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); BUSPIRONE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); PREDNISONE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); SALBUTAMOL SULFATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); TRAMADOL, TRAMADOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])		ICSR
EU-EC-1000851183	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 15 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hrress (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Neck pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Shock (84 - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	ELIGIUS (PARIBAN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); LEVOTHYROXINE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])		ICSR
EU-EC-1000851186	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardio-respiratory arrest (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Catheter sepsis (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastrointestinal wall thickening (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hematochezia (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hemoglobin decreased (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory arrest (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), White blood cell count increased (44 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	ACEFYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); ATORVASTATIN (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); CALCIUM ACETATE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); CARVEDILOL (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); CYANOCOBALAMIN (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); DIBAZEPIN (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); HYDROMORPHONE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); LIDOCANE, PRILICANE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); MACROGOL 3350 (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); MACROGOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350 (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); NITRAZEPAM, NITRAZEPAM BP (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); ROPINROLE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); TEMAZEPAM (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); TESTOSTERONE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); THIAMINE HYDROCHLORIDE, ASCORBIC ACID, BIOTIN, CALCIUM PANTOTHENATE, CYANOCOBALAMIN, FOLIC ACID, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown); ZINC (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); TRAZODONE, TRAZODONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 1DF] - Unknown)		ICSR
EU-EC-1000851199	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chest pain (n/a - Fatal - Results in Death), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	ACEFYLSALICYLIC ACID (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); ASCORBIC ACID (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); ATORVASTATIN (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); COLCALCIFEROL, CALCIUM CARBONATE (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); DISODIUM PHOSPHATE, SODIUM DIHYDROGEN PHOSPHATE ANHYDRICUS, DIHYDROGEN PHOSPHATE (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); DOCSALATE (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); DOCSALATE (C - Product used for unknown indication - Not applicable - [n/a - 40mg - Subcutaneous]); FUCCIDAN (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); INSULIN, INSULIN HUMAN (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); MIRTAZAPINE (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); PREDNISONE (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); RETINOL, THIAMINE HYDROCHLORIDE, ASCORBIC ACID, ERGOCALCIFEROL, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE, RETINOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); ZINC (C - Product used for unknown indication - Not applicable - [n/a - n/a - Unknown]); CARFAPRAZINE (C - Product used for unknown indication - Not applicable - [n/a - n/a - n/a]); SALBUTAMOL, SALBUTAMOL SULFATE (C - Product used for unknown indication - Not applicable - [n/a - n/a - n/a])		ICSR
EU-EC-1000851254	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Throat tightness (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	LEVEMIR (INSULIN DETEMIR) (C - Product used for unknown indication - n/a - [n/a - 60E] - Unknown); ACEFYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - 81mg - Unknown]); CALCIUM, CALCIUM ACETATE (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown]); CARVEDILOL (C - Product used for unknown indication - n/a - [n/a - 12.5mg - Unknown]); SULPIDIDE (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]); ISOSORBIDE MONONITRATE (C - Product used for unknown indication - n/a - [n/a - 30mg - Unknown]); LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]); BIMASTATIN (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown])		ICSR
EU-EC-1000851376	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 15 Years	Not Specified	Male	No	Asthma (n/a - Fatal - Results in Death), Asthma (n/a - Unknown -), Confusional state (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Malaria (n/a - Unknown -), Transient ischaemic attack (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular - More in ICSR)		ICSR	
EU-EC-1000851437	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Fatigue (n/a - Unknown - Other Medically Important Condition), Mouth haemorrhage (14 - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular - More in ICSR)	HYDROCHLOROTHIAZIDE, LOSARTAN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-1000851595	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chills (124 - Not Recovered/Not Resolved - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Fatigue (124 - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (124 - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (124 - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (124 - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	INSULIN GLARGINE [INSULIN GLARGINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); IRON (IRON) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); ACEFYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); AMODARONE, AMODARONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); ATORVASTATIN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); CLONIDINE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); COLCALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); DIBAZEPIN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); LABETALOL, LABETALOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); EMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); POTASSIUM POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); SERTRALINE, SERTRALINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); EPRONOLACTONE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-1000852037	03/05/2021	Spontaneous	Not Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000852263	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 15 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	PROBIOTICS NOS [PROBIOTICS NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]); EMEPRAZOLE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-1000852266	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 15 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), General physical health deterioration (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000852219	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Somnolence (n/a - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Hypertonia (14 - Not Recovered/Not Resolved -), Hypotonia (14 - Not Recovered/Not Resolved -), Musculoskeletal stiffness (14 - Not Recovered/Not Resolved -), Pain in extremity (14 - Not Recovered/Not Resolved -), Syncope (14 - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (14 - Not Recovered/Not Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR	
EU-EC-1000852248	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Arthritis (274 - Fatal - Results in Death), Arthritis (274 - Fatal - Results in Death), Cardiac arrest (274 - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Disorientation (274 - Fatal - Results in Death), Fall (274 - Fatal - Results in Death), Joint effusion (274 - Fatal - Results in Death), Joint injury (274 - Fatal - Results in Death), Nausea (274 - Fatal - Results in Death), Pain (274 - Fatal - Results in Death), Pneumonia (274 - Fatal - Results in Death), Sepsis (274 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	VAGRA [SILDENAFIL, SILDENAFIL CITRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]); ALENDRONATE SODIUM, ALENDRONATE SODIUM TRIHYDRATE, ALENDRONIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])		ICSR

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Implicated Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000852374	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Vomiting (274 - Fatal - Results in Death), Walking aid user (274 - Fatal - Results in Death), Cardiac failure (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (via - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), Pneumonia (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	LEVOPLOXACIN (LEVOPLOXACIN) (C - Product used for unknown indication - Unknown - [via - n/a - n/a]), LEVOTHYROXINE (LEVOTHYROXINE SODIUM) (C - Product used for unknown indication - Unknown - [via - n/a - n/a]), RIVAROXAN (RIVAROXAN SODIUM) (C - Product used for unknown indication - Unknown - [via - n/a - n/a]), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRHYDRATE (C - Hypochloroalkalium - n/a - [via - n/a - Unknown]), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF (C - Type 2 diabetes mellitus - n/a - [via - n/a - Unknown]), RANITIDINE, RANITIDINE HYDROCHLORIDE (C - Dyspepsia - n/a - [via - n/a - Unknown])	ICSR
EU-EC-1000852372	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Unresponsive to stimuli (via - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)		ICSR
EU-EC-1000852439	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	ICSR
EU-EC-1000852586	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	ICSR
EU-EC-1000852606	03/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	LEVETIRACETAM (LEVETIRACETAM) (C - Product used for unknown indication - n/a - [via - 1000mg - n/a]), TWOICAL HN (CARBOHYDRATES NOS, FIBRE, DIETARY, LIPIDS NOS, MINERALS NOS, PROTEINS NOS, VITAMINS NOS) (C - Product used for unknown indication - n/a - [via - 53mL - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [via - 10mg - n/a]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [via - 25mg - n/a]), [DOXUJATE SODIUM] (C - Product used for unknown indication - n/a - [via - 40mg - n/a]), [FAMOTIDINE] (C - Product used for unknown indication - n/a - [via - 40mg - n/a]), [ISOSORBIDE] (C - Product used for unknown indication - n/a - [via - 120mg - n/a]), [NACRODOL 33X] (C - Product used for unknown indication - n/a - [via - 17g - n/a])	ICSR
EU-EC-1000848213	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Cold sweat (via - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Dehydration (via - Unknown - Other Medically Important Condition), Malaise (via - Unknown - Other Medically Important Condition), Pyrexia (via - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000848028	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	ICARIDE (TELMSARTAN) (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [ATORVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [via - 25ug - Unknown]), [DUMESARTAN MEDOXIMIL, HYDROCHLOROTHAZIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [SOLFENACIN, SOLFENACIN SUCCLONATE] (C - Product used for unknown indication - n/a - [via - 5mg - Unknown]), [RIBESARTAN, RIBESARTAN] (C - Product used for unknown indication - n/a - [via - 150mg - Unknown]), [PROLIA (DENOSUMAB)] (C - Product used for unknown indication - n/a - [via - 60mg - Unknown]), [COLCALSIFEROL] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [via - 80ug - Unknown]), [ENAPRILEL] (C - Product used for unknown indication - n/a - [via - 20mg - Unknown]), [RETINOL, THIAMINE HYDROCHLORIDE, ASCORBIC ACID, ENOCALCIFEROL, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE, RETINOL] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [SINAVASTATIN] (C - Product used for unknown indication - n/a - [via - 40mg - Unknown]), [TITROPPIUM, TITROPPIUM BROMIDE, TITROPPIUM BROMIDE MONOHYDRATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [FLUTICASON, PROPRANOLOL, SALMETEROL, FLUTICASON PROPIONATE, SALMETEROL XINAFOATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [SABAPENTIN] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [HYDROCHLOROTHAZIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown])	ICSR
EU-EC-1000848781	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Concussion (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Fat (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumothorax (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulseless electrical activity (via - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	ICSR	
EU-EC-1000848960	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	ICSR	
EU-EC-1000848920	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Fatigue (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	ICSR
EU-EC-1000848939	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Asthma (64 - Unknown - Other Medically Important Condition), Confusional state (64 - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Dysstasia (14 - Unknown - Other Medically Important Condition), Epistaxis (14 - Unknown - Other Medically Important Condition), Fib (64 - Unknown - Other Medically Important Condition), Fatigue (14 - Unknown - Other Medically Important Condition), Lethargy (14 - Unknown - Other Medically Important Condition), Mouth haemorrhage (14 - Unknown - Other Medically Important Condition), Muscular weakness (64 - Unknown - Other Medically Important Condition), Respiratory arrest (14 - Unknown - Other Medically Important Condition), Visual impairment (64 - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	OLANZAPINE (OLANZAPINE) (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [ATENOLOL, ATENOLOL BPF] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [CARBAMAZEPINE, CARBAMAZEPINE (Pur. Eur.)] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [CLONAZEPAM] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [FLUCOXETINE, FLUCOXETINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [SABAPENTIN] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [LICHVASTATIN] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [via - n/a - Unknown])	ICSR
EU-EC-1000848940	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Myocardial infarction (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1000848843	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [ATORVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [CARMELLOSE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [DOXUJATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [FIBRIN CL] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [SUAMFENSIN] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [METOPFEN, METOPFEN HYDROGEN FUMARATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown])	ICSR
EU-EC-1000848963	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Hepatic mass (via - Unknown - Other Medically Important Condition), Pulmonary mass (via - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-1000848960	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (264 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Brain stress (264 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebral mass effect (264 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (264 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (264 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Motor dysfunction (264 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Movement disorder (264 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	CLONAZEPAM (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [BOPRINOL] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown])	ICSR
EU-EC-1000848962	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	ICSR
EU-EC-10008490195	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Hospitalisation (via - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	ICSR
EU-EC-10008490197	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Anaemia (64 - Unknown - Other Medically Important Condition), Cardiac disorder (64 - Unknown - Other Medically Important Condition), Cerebral small vessel ischaemic disease (64 - Unknown - Other Medically Important Condition), Chronic obstructive pulmonary disease (64 - Unknown - Other Medically Important Condition), Condition aggravated (64 - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death), Hepatic enzyme abnormal (64 - Unknown - Other Medically Important Condition), Hypertension (64 - Unknown - Other Medically Important Condition), Hypokalaemia (64 - Unknown - Other Medically Important Condition), Hypothyroidism (64 - Unknown - Other Medically Important Condition), Malnutrition (64 - Unknown - Other Medically Important Condition), Mental disorder (64 - Unknown - Other Medically Important Condition), Thrombosis (64 - Unknown - Other Medically Important Condition), Tumor (via - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000849049	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Acute myeloid leukaemia (114 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (114 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (114 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	ICSR
EU-EC-1000849048	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	ICSR
EU-EC-10008490602	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	ICSR
EU-EC-10008490677	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (via - Unknown - Caused/Prolonged Hospitalisation), Anemia (via - Unknown - Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), Generalised oedema (284 - Unknown - Caused/Prolonged Hospitalisation), Hyperhaemostasis (284 - Unknown - Caused/Prolonged Hospitalisation), Hypermagnesaemia (284 - Unknown - Caused/Prolonged Hospitalisation), Mental status changes (284 - Unknown - Caused/Prolonged Hospitalisation), Pulmonary oedema (284 - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	ICSR
EU-EC-10008490900	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac arrest (via - Unknown - Other Medically Important Condition), Death (14 - Fatal - Results in Death), Respiratory arrest (via - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular - More in ICSR)	Not reported	ICSR
EU-EC-10008491158	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Bacteremia (via - Unknown - Other Medically Important Condition), Chronic obstructive pulmonary disease (via - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death), Dyspnoea (via - Unknown - Other Medically Important Condition), Respiratory disorder (via - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	ICSR
EU-EC-10008491299	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Arrows (via - Fatal - Results in Death), Asthma (via - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Dyspnoea (via - Fatal - Results in Death), Heart rate abnormal (via - Fatal - Results in Death), Malaise (via - Fatal - Results in Death), Pain in extremity (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	[BIOTIN] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [CYANOCOBALAMIN, FOLIC ACID] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - Product used for unknown indication - n/a - [via - n/a - n/a])	ICSR
EU-EC-10008491470	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10008491499	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death), Mobility decreased (via - Unknown - Other Medically Important Condition), Vaccination complication (via - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10008491755	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10008492799	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10008493042	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Malaise (24 - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Unknown)	Not reported	ICSR
EU-EC-10008493092	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10008493133	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10008493139	30/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Swelling (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DF] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [FENOFIBRATE, FENOFIBRATE MICROEMULSION] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [LABETALOL, LABETALOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [MECOBAMIN] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [CARBIDOPA, LEVODOPA (CARBIDOPA, LEVODOPA)] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [KETOCOCONAZOLE (NETOCONAZOLE)] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [ATOMOXETINE, ATOMOXETINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [ATOMOXETINE] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [BACLOFEN] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [BUSPIRONE] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [SALICYPYRROL] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [CELEBREX] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [COLESTIPOL] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [DOXEPIN, DOXEPIN HYDROCHLORIDE, DOXEPIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [ESTROGENS CONJUGATED, ESTROGEN SODIUM SULFATE, EQUILIN SULFATE SODIUM] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [FAMOTIDINE] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [SABAPENTIN] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [LABETALOL, LABETALOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown), [DIXYDOLONE, OXYCODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - 1DF] - Unknown)	

EU Local Number	EV Summary Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Age Group	Sex	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Involved Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1000483780	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death), Hemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), Urinary tract infection (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Product used for unknown indication - Not applicable - [n/a - 75mg - Oral], MELATONIN [MELATONIN] (C - Sleep disorder - n/a - [n/a - 5mg - Oral], ATORVASTATIN [C - Hyperlipaemia - n/a - [n/a - 20mg - Oral], CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - Not applicable - [n/a - 10mg - Oral], HYDROCHLOROTHIAZIDE, LISINAPRIL] (C - Hypertension - Unknown - [n/a - n/a - Oral], LEVOTHYRONINE, LEVOTHYRONINE SODIUM] (C - Hypothyroidism - Not applicable - [n/a - n/a - Oral], WARFARIN, WARFARIN SODIUM] (C - Thrombosis prophylaxis - n/a - [n/a - n/a - Oral]	CSR
EU-EC-1000484296	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000484297	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Death (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000484612	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000485109	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Chest pain (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000485246	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000485280	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000485376	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Chills (n/a - Unknown -), Death (1d - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Injection site pain (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	ACEFYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DOLACALFERROL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), HYDROCHLOROTHIAZIDE, SPIRONOLACTONE] (C - Hypertension - n/a - [n/a - n/a - Oral], [LORAZEPAM] (C - Product used for unknown indication - n/a - [n/a - 05mg - Oral], METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 150mg - Oral], PRAVASTATIN SODIUM] (C - Blood cholesterol increased - n/a - [n/a - 10mg - Oral]	CSR
EU-EC-1000485397	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Cerebrovascular accident (1d - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Hepatic failure (1d - Unknown - Other Medically Important Condition), Pulmonary embolism (1d - Unknown - Other Medically Important Condition), Renal failure (1d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SOTALOL, SOTALOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000485455	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000485607	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	VALSARTAN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000485641	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000485679	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000481327	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000481492	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000481776	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000482004	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000482005	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000482143	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000482239	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000482342	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DOLACALFERROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), HYDROCHLOROTHIAZIDE, LISINAPRIL, HYDROCHLOROTHIAZIDE, LISINAPRIL ANHYDROUS, LISINAPRIL ANHYDROUS, HYDROCHLOROTHIAZIDE EP, LISINAPRIL DIHYDRATE, HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [INSULIN HUMAN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NFEDIPINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000482422	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000482833	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000483001	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000483729	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	ACEFYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ANHYDROUS NALOXONE HYDROCHLORIDE, NALOXONE, NALOXONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FISH OIL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SAMBENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [GLYCERYL TRINITRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [IPRATROPIUM BROMIDE, SALBUTAMOL, SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE, SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE MONOHYDRATE, SALBUTAMOL, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LACTULOSE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LORATADINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [MONIFLUMATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NISTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NIMETRAZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TRAMACOL, TRAMACOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000486789	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000489173	2014/201	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	[DXYGEN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000489242	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-1000489313	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000489396	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death), Fatigue (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	CIALIS [TADALAFIL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FEMSOLOLIMAB [FEMSOLOLIMAB] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), AMOXICILLIN SODIUM, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID, AMOXICILLIN, POTASSIUM CLAVULANATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LEVOTHYRONINE, LEVOTHYRONINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METFORMIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000489882	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male No Death (n/a - Fatal - Results in Death), Syncope (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000491346	2014/201	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male No Death (0d - Fatal - Results in Death)	SPRIVEX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - Not applicable - [n/a - 5mL - Intramuscular])	[ALLOPURINOL] (C - n/a - n/a -), [ALPRAZOLAM] (C - n/a - n/a -), [BISOPROLOL FUMARATE] (C - n/a - n/a -), [ESCITALOPRAM] (C - n/a - n/a -), [VALSARTAN, HYDROCHLOROTHIAZIDE] (C - n/a - n/a -)	CSR
EU-EC-1000491362	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death), Fever (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000491779	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000491730	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death), Unresponsive to stimuli (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	LANTUS [INSULIN GLARGINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MELATONIN [MELATONIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM BESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ACEFYLSALICYLIC ACID, ASPIRIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ETIDRINE DIHYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DOLACALFERROL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEZETIMBE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FERROUS SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPIONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [IPRATROPIUM BROMIDE MONOHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MACRODOL 3350] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL SUCCINATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL SUCCINATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DODATRIOL HYDROCHLORIDE, TROPICAMID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PAROXETINE, PAROXETINE HYDROCHLORIDE, PAROXETINE HYDROCHLORIDE ANHYDROUS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SUCRALFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TAMBULOGEN, TAMBULOGEN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000491660	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-1000491669	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-1000492466	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	AEROSOL SRTZNER [CAMPHOR, ESSENTIAL OILS NDC] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ETIPRAT] (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), [DOLACALFERROL] (C - Product used for unknown indication - n/a - [n/a - 1000DP] - n/a), [CYANOCOBALAMIN, FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a - 1DP] - n/a), [DLTAZEM, DLTAZEM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LORATADINE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10DP] - n/a), [SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [GLUCOPRIL] (C - Diabetes mellitus - n/a - [n/a - 5mg - n/a]), [METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - n/a])	CSR
EU-EC-1000493064	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-1000493331	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	SPRIVEX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000493134	2014/201	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n		

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Age Group	Sex	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form		
								<p>Chills (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Cholelithiasis (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Death (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Decreased appetite (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Delirium (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Diastolic dysfunction (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Dyslipidaemia (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Endocarditis staphylococcal (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>General physical health deterioration (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Hemiparesis (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Hepatosplenomegaly (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Hypernatremia (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Hypokalaemia (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Hypotension (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Hypoxia (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Inferior vena cava distention (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Iron deficiency anaemia (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Lactic acidosis (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Lung opacity (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Lung oedema (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Mental status changes (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Mitral valve incompetence (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Nausea (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Obesity (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Pleural effusion (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Polymyoma (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Sepsis shock (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Staphylococcal infection (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Thrombocytopenia (15645min - Fatal - Results in Death, Caused/Prolonged Hospitalisation)</p>					
EU-EC-100043922	2034/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (via - Fatal - Results in Death), Dyspnoea (via - Not Recovered/Not Resolved -), Headache (via - Not Recovered/Not Resolved -), Limb discomfort (via - Not Recovered/Not Resolved -), Productive cough (via - Not Recovered/Not Resolved -)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - Immunisation - via - n/a - n/a - n/a)	Not reported	ICSR
EU-EC-100043970	2034/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (via - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - via - n/a - n/a - n/a)	Not reported	ICSR
EU-EC-100044032	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Asthma (via - Unknown -), Death (1d - Fatal - Results in Death), Diarrhoea (via - Unknown -), Fulfil (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	PROPANOLOL HYDROCHLORIDE (PROPRANOLOL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [CETIRIZINE DIHYDROCHLORIDE] (C - Rhinitis allergic - n/a - [via - 10mg - Oral]), [FERROUS SULFATE] (C - Iron deficiency anaemia - n/a - [via - 325mg - Oral]), [FLUTICASON] (C - Rhinitis allergic - n/a - [via - n/a - Nasal]), [SABAFENTIN] (C - Back pain - n/a - [via - 120mg - Unknown]), [LAMOTRIGINE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [METHOCARBAMOL] (C - Back pain - n/a - [via - 500mg - Oral]), [PIANTOPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [via - 40mg - Oral]), [SUCCALFATE] (C - Gastroesophageal reflux disease - n/a - [via - 2mg - Oral]), [VALICLOXICID] (C - Product used for unknown indication - n/a - [via - 1mg - n/a])	ICSR
EU-EC-100043945	2034/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Hepes zoster (via - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100040731	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), SARS-CoV-2 test positive (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100043938	2034/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100041059	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lethargy (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Symptomatic bradycardia (via - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	INSULIN GLARGINE (INSULIN GLARGINE) (C - Product used for unknown indication - n/a - [via - 100DP] - Unknown), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [via - 20mg - Unknown]), [HYDRALAZINE] (C - Product used for unknown indication - n/a - [via - 50mg - Unknown]), [LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [via - 100mg - Unknown]), [LOVASTATIN] (C - Product used for unknown indication - n/a - [via - 20mg - Unknown]), [METFORMIN, METHFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [via - 1000mg - Unknown]), [METHOPRAZOLE] (C - Product used for unknown indication - n/a - [via - 20mg - Unknown])	ICSR
EU-EC-100041211	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal discomfort (via - Fatal - Results in Death), Death (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100041297	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Acute myocardial infarction (M - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	BRIMONIDE (C - Glaucoma - n/a - [via - n/a - Ophthalmic]), [CLOXIFENE SODIUM] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [HYDROXYMELLOSE, GLYCEROL, MACROGOL 400, POLYVINYLOXOLONE, PROPYLENE GLYCOL, VASELINE, LIQUID PARAFFIN] (C - Dry eye - n/a - [via - 5.6% - Ophthalmic]), [PARACETAMOL] (C - Pain in extremity - n/a - [via - 1300mg - Unknown])	ICSR
EU-EC-100041197	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death), Feeling hot (via - Unknown -), Nervousness (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100041109	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Aphasia (via - Fatal - Results in Death), Death (via - Fatal - Results in Death, Other Medically Important Condition), Feeling of body temperature change (via - Fatal - Results in Death), Hyperhidrosis (via - Fatal - Results in Death), Musculoskeletal stiffness (via - Fatal - Results in Death), Peripheral coldness (via - Fatal - Results in Death), Staring (via - Fatal - Results in Death), Tremor (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100041254	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Decreased appetite (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	MELATONIN (MELATONIN) (C - Product used for unknown indication - n/a - [via - 3mg - n/a]), [DOXUSATE] (C - Product used for unknown indication - n/a - [via - 100mg - n/a]), [FINASTERIDE] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [ROBUVASTATIN, ROBUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [via - 40mg - n/a]), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - n/a - n/a])	ICSR
EU-EC-100041490	2034/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (via - Fatal - Results in Death), Death (via - Fatal - Results in Death), Diarrhoea (via - Fatal - Results in Death), Fulfil (via - Fatal - Results in Death), Cough (via - Unknown -), Death (1d - Fatal - Results in Death), Dyspnoea (1d - Unknown -), Respiratory arrest (1d - Unknown - Other Medically Important Condition), Respiratory tract congestion (via - Unknown -), Rhinitis (via - Unknown -), Suspected COVID-19 (via - Unknown -), Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - n/a - [via - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100039560	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death), Diarrhoea (via - Unknown -), Dyspnoea (1d - Unknown -), Respiratory arrest (1d - Unknown - Other Medically Important Condition), Respiratory tract congestion (via - Unknown -), Rhinitis (via - Unknown -), Suspected COVID-19 (via - Unknown -), Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100039592	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition), Cervical (via - Unknown - Other Medically Important Condition), Death (via - Fatal - Results in Death), Rash (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100039431	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac failure (2d - Unknown - Caused/Prolonged Hospitalisation), Death (2d - Fatal - Results in Death), Hypotension (2d - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	ATORVASTATIN (C - Product used for unknown indication - n/a - [via - 20mg - Unknown]), [BUSPIRONE] (C - Product used for unknown indication - n/a - [via - 10mg - Unknown]), [CLONAZEPAM] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [DOXUSATE] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [DONEPEZIL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - 10mg - Unknown]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [via - 100ug - Unknown]), [LISINAPRIL, LISINAPRILATE] (C - Product used for unknown indication - n/a - [via - 2.5mg - Unknown]), [NIFEDIPINE] (C - Product used for unknown indication - n/a - [via - 5mg - Unknown]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - 50mg - Unknown]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [via - 75mg - Unknown])	ICSR
EU-EC-100039624	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100039685	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100039695	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Dyspnoea (via - Unknown -), Memory impairment (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100039730	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Body temperature increased (via - Unknown -), Death (via - Fatal - Results in Death), Headache (via - Unknown -), Pain (via - Unknown -), Urinary tract infection (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100039790	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (via - Fatal - Results in Death), Myocardial infarction (1d - Fatal - Results in Death, Life Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[SABAFENTIN] (C - Product used for unknown indication - n/a - [via - n/a - Unknown])	ICSR
EU-EC-100039707	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cardiomegaly (via - Unknown - Caused/Prolonged Hospitalisation), Death (via - Fatal - Results in Death), Escherichia infection (via - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (via - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (via - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - Not applicable - [via - 81mg - n/a]), [AMLODIPINE BESILATE] (C - Product used for unknown indication - Not applicable - [via - n/a - n/a]), [PARACETAMOL] (C - Product used for unknown indication - Not applicable - [via - 500mg - n/a])	ICSR
EU-EC-100039847	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100039814	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[CYPROHEPTADINE HYDROCHLORIDE, CYPROHEPTADINE HYDROCHLORIDE, ANHYDROUS] (C - Product used for unknown indication - n/a - [via - 2DP] - Oral), [FOLIC ACID] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - [via - 1DP] - Oral), [METHYLDONATE] (C - Product used for unknown indication - n/a - [via - 3DP] - Oral)	ICSR
EU-EC-100039827	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100039861	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Arthralgia (via - Unknown -), Chest pain (via - Unknown -), Death (1d - Fatal - Results in Death), Diarrhoea (via - Unknown -), Headache (via - Unknown -), Malaise (via - Unknown -), Pain (via - Unknown -), Vomiting (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100039818	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (via - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100039850	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (via - Unknown -), Chills (via - Unknown -), Death (via - Fatal - Results in Death), Malaise (via - Unknown -), Pulse absent (via - Unknown -), Pyrexia (via - Unknown -), Respiratory arrest (via - Unknown - Other Medically Important Condition), Unresponsive to stimuli (via - Unknown - Other Medically Important Condition), Vomiting (via - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	TRILICITY [DULAGLUTIDE] (C - n/a - n/a - [via - n/a - n/a])	ICSR
EU-EC-100039879	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Female	No	Cardiac arrest (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Syncope (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100039877	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	15-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	Not reported	ICSR
EU-EC-100040063	2034/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [via - 1DP] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [via - 81mg - Unknown]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [via - 2.5mg - Unknown]), [CEFALEXIN, CEFALEXIN MONOHYDRATE] (C - Product used for unknown indication - n/a - [via - 250mg - Unknown]), [SABAFENTIN] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [BIPROTRIUM BROMIDE] (C - Product used for unknown indication - n/a - [via - 2% - Unknown]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [via - 25mg - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [via - n/a - Unknown]), [SULFADIAZINE SILVER] (C - Product used for unknown indication - n/a - [via - 1% - Unknown]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [via - n/a - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [via - n/a - n/a])	ICSR

EU Local Number	EY Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Purpose	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Chn	Patent Rpt	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
												[CANNABIS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [CHLORPHENAMINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [DABEPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [GLIPIZIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [MOXETASONE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]). [ONDANSETRON] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]).			
EU-EC-1000401370	2204/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)	TERAZOSIN, TERAZOSIN HYDROCHLORIDE DIPHYRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]) [DABEPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR	
EU-EC-1000403809	2204/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)	ARIPY (ARIPRAZOLE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CYMBALTA (DULOXETINE, DULOXETINE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), INCRUSE ELLIPTA (MEDIATORUM BROMIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [CLONIDINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FLUTICASON FURTOATE, VILANTEROL, TRIFENATATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDRAZINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ISOSORBIDE MONONITRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LABETALOL, LABETALOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LEVOTHYRAXINE, LEVOTHYRAXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NIFEDIPINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SALICYLAMOL, SALICYLAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [INSULIN, INSULIN HUMANA] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-1000405546	2204/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death), Pain in extremity (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000405754	2204/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000303646	2104/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (1d - Fatal - Results in Death), Fatigue (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000303276	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Chills (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Pyrexia (n/a - Unknown - Other Medically Important Condition), Tumor (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000303304	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000304232	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)	PREGABALIN (PREGABALIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), XARELTO (RIVAROXABAN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), HYDROCODONE BITARTRATE, PARACETAMOL (C - n/a - n/a - [n/a - n/a - Unknown]), LEVOTHYRAXINE, LEVOTHYRAXINE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [MORPHINE SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [VITAMIN D] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])		ICSR
EU-EC-1000305739	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)	[VITAMIN D] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NICOTIAMINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SODIUM HYDROGEN CARBONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [VITAMIN D] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR	
EU-EC-1000306476	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death), Seizure (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000306895	2104/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000307803	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000307950	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (1d - Fatal - Results in Death), General physical health deterioration (1d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)	[RISERTAN (RISERTAN)] (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a]), [METOPROLOL SUCONATE, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a])	ICSR	
EU-EC-1000308073	2104/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)	HIMALOG (INSULIN LISPRO) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LANTUS (INSULIN GLARGINE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ATORVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [BENZONATATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDRAZINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LORATADINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METGLAZONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NIFEDIPINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SALICYLAMOL, SALICYLAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [INSULIN, INSULIN HUMANA] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-1000308181	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000308348	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (1d - Fatal - Results in Death), Fatigue (n/a - Unknown -), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000308434	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000308976	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309952	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309241	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309348	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309528	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309608	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Chills (n/a - Unknown -), Death (1d - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -), Food refusal (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -), Respiratory rate increased (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309657	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309704	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309810	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309377	2104/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Asthma (n/a - Unknown - Other Medically Important Condition), Bedridden (n/a - Unknown - Disability), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Life Threatening), Pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved -), Somnolence (n/a - Unknown - Life Threatening), Thirst (n/a - Unknown - Other Medically Important Condition)	SPRIVEV (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)	PREGABALIN (PREGABALIN) (C - Product used for unknown indication - Dose not changed - [n/a - 75mg - Oral]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - Not applicable - [n/a - 100mg - Oral]), [FLUOXETINE SODIUM] (C - Product used for unknown indication - Dose not changed - [n/a - 20mg - Oral]), [LOSARTAN POTASSIUM] (C - Product used for unknown indication - Dose not changed - [n/a - 50mg - Oral]), [MAGNESIUM ASPARTATE HYDROCHLORIDE] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - Oral]), [METANIZOL SODIUM] (C - Product used for unknown indication - Dose not changed - [n/a - 500mg - Oral]), [NALOXONE HYDROCHLORIDE] (C - Product used for unknown indication - Dose not changed - [n/a - 10mg - Oral]), [PARACETAMOL] (C - Product used for unknown indication - Dose not changed - [n/a - 500mg - Oral]), [PREDNISOLONE] (C - Product used for unknown indication - Dose not changed - [n/a - 5mg - Oral]), [SODIUM HYDROGEN CARBONATE] (C - Product used for unknown indication - Dose not changed - [n/a - n/a - Oral]), [TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - Dose not changed - [n/a - 4mg - Oral]), [TORSEMIDE] (C - Product used for unknown indication - Dose not changed - [n/a - 10mg - Oral]), CANNABIS (CANNABIS) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), RISERTAN (RISERTAN) (C - Hypertension - n/a - [n/a - 30mg - n/a]), IRON (IRON) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LEFLUNOMIDE (LEFLUNOMIDE) (C - Rheumatoid arthritis - n/a - [n/a - 10mg - n/a]), RINVOO (LIFAVIPRIN) (C - Rheumatoid arthritis - n/a - [n/a - 50mg - n/a]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DIAZEPAM] (C - Product used for unknown indication - n/a - [n/a - 15mg - n/a]), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - Chest pain, Hypertension - n/a - [n/a - 300mg - n/a]), [DABEPENTIN] (C - Nourgia - n/a - [n/a - 360mg - n/a]), [LANCOPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 30mg - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - 10mg - n/a]), [ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIPHYRATE] (C - Nausea - n/a - [n/a - 8mg - n/a]), [DIPYRIDONE, DIPYRIDONE HYDROCHLORIDE] (C - Pain - n/a - [n/a - 40mg - n/a]), [PILCOPRINE, PILCOPRINE HYDROCHLORIDE] (C - Dry mouth - n/a - [n/a - 20mg - n/a]), [PROCHLORPERAZINE, PROCHLORPERAZINE MALEATE] (C - Nausea - n/a - [n/a - 10mg - n/a]), [SUMATRIPTAN, SUMATRIPTAN SUCONATE] (C - Migraine - n/a - [n/a - 50mg - n/a]), [TZANIDINE] (C - Muscle spasms - n/a - [n/a - 4mg - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 12.5mg - n/a])		ICSR
EU-EC-1000309509	2004/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Chest pain (3d - Unknown -), Death (1d - Fatal - Results in Death), Fatigue (n/a - Unknown -), Influenza like illness (3d - Unknown -), Vaccination site pain (6d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)	CANNABIS (CANNABIS) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), RISERTAN (RISERTAN) (C - Hypertension - n/a - [n/a - 30mg - n/a]), IRON (IRON) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LEFLUNOMIDE (LEFLUNOMIDE) (C - Rheumatoid arthritis - n/a - [n/a - 10mg - n/a]), RINVOO (LIFAVIPRIN) (C - Rheumatoid arthritis - n/a - [n/a - 50mg - n/a]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DIAZEPAM] (C - Product used for unknown indication - n/a - [n/a - 15mg - n/a]), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - Chest pain, Hypertension - n/a - [n/a - 300mg - n/a]), [DABEPENTIN] (C - Nourgia - n/a - [n/a - 360mg - n/a]), [LANCOPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 30mg - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - 10mg - n/a]), [ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIPHYRATE] (C - Nausea - n/a - [n/a - 8mg - n/a]), [DIPYRIDONE, DIPYRIDONE HYDROCHLORIDE] (C - Pain - n/a - [n/a - 40mg - n/a]), [PILCOPRINE, PILCOPRINE HYDROCHLORIDE] (C - Dry mouth - n/a - [n/a - 20mg - n/a]), [PROCHLORPERAZINE, PROCHLORPERAZINE MALEATE] (C - Nausea - n/a - [n/a - 10mg - n/a]), [SUMATRIPTAN, SUMATRIPTAN SUCONATE] (C - Migraine - n/a - [n/a - 50mg - n/a]), [TZANIDINE] (C - Muscle spasms - n/a - [n/a - 4mg - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 12.5mg - n/a])		ICSR
EU-EC-1000309792	2004/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death), Fatigue (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309999	2004/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000308008	2004/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000308485	1904/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	No	Death (n/a - Fatal - Results in Death), Dyspnoea (5d - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (5d - Not Recovered/Not Resolved -)	SPRIVEV (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309021	1904/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Cheyne-Stokes respiration (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown -), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (n/a - Unknown - Other Medically Important Condition), Ventricular tachycardia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)	[ENOXAPARIN, ENOXAPARIN SODIUM] (C - n/a - Not applicable - [n/a - 70mg - Subcutaneous]), [PIPERACILLIN, TZOBACTAM] (C - n/a - Not applicable - [13d - 10.125g - Intravenous (not otherwise specified)])	ICSR	
EU-EC-1000309086	1904/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309087	1904/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)		ICSR	
EU-EC-1000309215	1904/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	No	Abdominal distension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Hypnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				

EU Local Number	EY Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group (as per reporter)	Patent Age Group (as per reporter)	Patent Sex	Patent Chirality	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Retracting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
			Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Hepato zoster (n/a - Unknown -)	VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-100083646	19/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-100083673	19/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	LEVEMIR (INSULIN DETEMIR) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [KARLETO (RIVAROXABAN)] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPRIOLOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [NEMPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-100083685	19/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000836478	19/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000836458	19/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000836461	19/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (5th - Fatal - Results in Death), Dysphagia (3d - Unknown - Life Threatening, Other Medically Important Condition), Feeding disorder (3d - Unknown - Life Threatening, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [GUAFENESIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LINALOLOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MACRODOL 3300] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MELOXICAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SIBASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [HALPROIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [CALCIOTRINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MODURINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [RALOXIFENE] (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000836462	19/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000836561	19/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Fat (n/a - Unknown - Caused/Prolonged Hospitalisation), Hepatic encephalopathy (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-100083753	16/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPIREVA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	CELECOXIB (CELECOXIB) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE)] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FELODIPINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDROCHLOROTHIAZIDE, ANHYDROUS AMLODIPINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [METOPROLOL, SUCRONATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NEMPRAZOLE] (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), [TAMSOLOL HYDROCHLORIDE, DUSTATENSIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000836916	16/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000836418	16/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000833478	16/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	SPIREVA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - n/a - n/a - [n/a - 5mL - Intramuscular])	Not reported	CSR
EU-EC-1000833526	16/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000836204	16/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Nausea (n/a - Unknown -), Unresponsive to stimuli (1d - Fatal - Results in Death), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000836329	16/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000837932	16/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Feeling cold (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000837933	16/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000831254	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000831727	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000831722	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000831729	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chest pain (1d - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Refusal of treatment by patient (1d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000831824	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10008318748	15/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Body temperature decreased (n/a - Unknown -), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Salivary hypersecretion (1d - Recovered/Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - n/a)	[DEXANSOPRAZOLE, LANSOPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - 60mg - Unknown]), [FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), [ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - 30mg - Unknown]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-10008318750	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10008318930	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10008319313	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - 50mg - Oral])	CSR
EU-EC-1000832081	15/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-1000832400	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Back pain (n/a - Unknown -), Carditis infection (n/a - Unknown -), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Dysuria (n/a - Unknown -), Feeling abnormal (n/a - Unknown -), Hematuria (n/a - Unknown - Other Medically Important Condition), Urinary tract infection (n/a - Unknown -), White blood cell disorder (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[FLUTICASON FURATE, VILANTEROL TRIFENATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SABAFENTIN] (C - Product used for unknown indication - n/a - [n/a - 1600mg - n/a]), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SPRONOLACTONE] (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), [TRIMENINE] (C - Product used for unknown indication - n/a - [n/a - 4mg - Unknown]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a]), [TRAZOLONE, TRAZOLONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a])	CSR
EU-EC-1000832428	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000832442	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[MIRCEA (METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA)] (C - Product used for unknown indication - n/a - [n/a - 300mg - Intramuscular]), [DUCOSATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown]), [FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), [GENTAMICIN, GENTAMICIN SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Topical]), [HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 75mg - Unknown]), [LACTOBACILLUS RHAMNOSUS GQ] (C - Product used for unknown indication - n/a - [n/a - 1DP] - Unknown), [LACTULOSE] (C - Product used for unknown indication - n/a - [n/a - 120mL - Unknown]), [NEMPRAZOLE, NEMPRAZOLE MAGNESIUM] (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown])	CSR
EU-EC-1000832470	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Insomnia (n/a - Unknown -), Respiration abnormal (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - Non n/a - CSR)	[PREDNISONE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DOLICALCIPROLOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [FAMCICLOVIR] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SILICLOSAMINE, CHONDROITIN SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [MELOXICAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10008324517	15/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Transplant (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10008301528	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000830521	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Chronic obstructive pulmonary disease (1d - Fatal - Results in Death), Cognitive disorder (1d - Fatal - Results in Death), Condition aggravated (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10008307474	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10008307475	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Traumatic intracranial haemorrhage (4d - Fatal - Results in Death)	SPIREVA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [LITHIUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a - 450mg - n/a]), [DIURETIC FUMARATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), [SODIUM VALPROATE] (C - Product used for unknown indication - n/a - [n/a - 1200mg - n/a]), [SODIUM VALPROATE] (C - Product used for unknown indication - n/a - [n/a - 150mg - n/a])	CSR
EU-EC-10008307494	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Abcess limb (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Increased activity (1d - Fatal - Results in Death), Grown abcess (1d - Fatal - Results in Death), Increased upper airway secretion (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000830908	14/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10008309496													

EU Local Number	EV Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group (as per reporter)	Patent Sex	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Intervening Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-1000310316	14/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Alanine aminotransferase increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Aspartate aminotransferase increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Asthma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dysphagia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Troponin increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ESOMEPRAZOLE (ESOMEPRAZOLE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), NADOLOL (C - Hypertension - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-100031054	14/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000311292	14/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000311725	14/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	16-64 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000311910	14/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000311966	14/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000312005	14/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000312007	14/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000289274	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000289276	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	FENTANYL, FENTANYL, FENTANYL CITRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Transdermal]), PROPETHAZINE, PROPETHAZINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-1000289287	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Male	No Abdominal pain (n/a - Fatal - Results in Death), Atrragia (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Epilepsia (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Feeling abnormal (n/a - Fatal - Results in Death), Mouth haemorrhage (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pain (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000289336	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000289338	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a])	ICSR
EU-EC-1000289305	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000289308	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No Absence of immediate treatment response (n/a - Unknown - Caused/Prolonged Hospitalisation), Biliary colic (n/a - Unknown - Caused/Prolonged Hospitalisation), Cholelithiasis (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Lung disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal disorder (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), AMLODIPINE BESILATE, ATORVASTATIN CALCIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ASCORBIC ACID, CITRUS BIOFLAVONOIDS (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DEXYRITHORPHAN HYDROBROMIDE, PHENYLEPHRINE HYDROCHLORIDE, GUAFENESIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FERROUS SULFATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (NOSTOL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (INSULIN, INSULIN HUMAN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (LORAZEPAM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), METFORMIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-1000289349	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Chills (n/a - Fatal - Results in Death), Diarrhea (n/a - Fatal - Results in Death), Disorientation (n/a - Fatal - Results in Death), Vital functions abnormal (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	ACRYVASTINE, DIPHENHYDRAMINE HYDROCHLORIDE, DIPHENHYDRAMINE HYDROCHLORIDE, ZINC ACETATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), DONSPEL (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), MIFYAZIPINE (C - Product used for unknown indication - n/a - [n/a - 30mg - n/a]), RISPERIDONE (C - Product used for unknown indication - n/a - [n/a - 1mg - n/a]), TEMAZEPAM (C - Product used for unknown indication - n/a - [n/a - 30mg - n/a])	ICSR
EU-EC-1000292050	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000292054	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000292055	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000292063	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	16-64 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000292101	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	16-64 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000292103	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000292114	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No Anoxemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Chronic obstructive pulmonary disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Coronary artery disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dementia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000292124	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000292850	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death), Dysphagia (n/a - Unknown -), Hypernatremia (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	SENA (SENNOSIDE A+B) (SENNOSIDE A+B) (C - n/a - Does not changed - [n/a - n/a - n/a])	ICSR
EU-EC-1000292870	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000292970	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Ventricular arrhythmia (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (FLUTICASON PROPIONATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SENA, ALEXANDRIAN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000292978	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	16-64 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000292990	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	16-64 Years	Not Specified	Female	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000292999	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	SPIREVA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	ATORVASTATIN CALCIUM (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), BISOPROLOL FUMARATE (C - Product used for unknown indication - n/a - [n/a - 2.5mg - Unknown - More in CSRS]), DELTAZEM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 180mg - Unknown]), PHENPROLOLUMON (C - Product used for unknown indication - n/a - [n/a - 3mg - Unknown])	ICSR
EU-EC-1000293118	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000293335	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000293437	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000293538	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death), Intentional dose omission (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000293713	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000293815	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	CARVEDILOL (C - n/a - n/a -), FUROSEMIDE (C - n/a - n/a -)	ICSR
EU-EC-1000293889	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000294030	13/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Acute left ventricular failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Peripartum ischaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripartum swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Skin weeping (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000295550	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No Agonox (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Heart rate irregular (n/a - Unknown -), Hypoglycaemia (n/a - Unknown -), Hypotension (n/a - Unknown -), Irritability (n/a - Unknown -), Lethargy (n/a - Unknown -), Malaise (n/a - Unknown -), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	(CARBOHYDRATES NOS) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (CHOLESTEROL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (DOXILATE SODIUM, CADO) (C - n/a - n/a -), (FAT) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (GENTAMICIN, GENTAMICIN SULFATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (GUAFENESIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (HALOPERIDOL, HALOPERIDOL DECANATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (LOPERAMIDE HYDROCHLORIDE, LOPERAMIDE OXIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (LORAZEPAM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (MACRODOL 330) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (MAGNESIUM HYDROXIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (MINERALS NOS) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (NYSTATIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (PARACETAMOL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (RISPERIDONE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (TITANINE NOS) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (VALIUM, VALIUM MALEATE) (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), (DIPYRIDOLE) (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), (EPRONOLACTONE) (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a])	ICSR
EU-EC-1000296290	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000296327	13/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	16-64 Years	Not Specified	Male	No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000296421	12/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR
EU-EC-1000296796	12/04/2021											

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Parent Child	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Subsequent Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-1008253396	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008253361	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac arrest (19h - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - n/a - n/a - [n/a] - n/a - n/a)	Not reported	ICSR
EU-EC-1008254024	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Asthma (n/a - Unknown -), Death (4d - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Productive cough (n/a - Unknown -), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	KEPPRA (LEVETIRACETAM) (C - Product used for unknown indication - n/a - [n/a] - 1000mg - Unknown), CYCLOBENZAPRINE, CYCLOBENZAPRINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), VITAMINS NOS (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	ICSR
EU-EC-1008254026	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Asthma (n/a - Unknown -), Crying (1wk - Unknown -), Death (n/a - Fatal - Results in Death), Gait disturbance (n/a - Unknown -), General physical health deterioration (n/a - Unknown -), Walking aid user (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	DONEPEZIL (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	ICSR
EU-EC-1008254253	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008254261	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008255174	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008255347	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	GLYCOPHYRONIUM BROMIDE (GLYCOPHYRONIUM BROMIDE) (C - Product used for unknown indication - Dose not changed - [n/a] - n/a - Nasal), MELATONIN (MELATONIN) (C - Product used for unknown indication - Dose not changed - [n/a] - n/a - Oral), AMLODIPINE MESILATE (C - Product used for unknown indication - Dose not changed - [n/a] - n/a - Oral), COLECALCIFEROL (C - Product used for unknown indication - Dose not changed - [n/a] - n/a - Oral), VITAMINS NOS (C - Product used for unknown indication - Dose not changed - [n/a] - n/a - Oral)	ICSR
EU-EC-1008255629	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008255586	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	ABIFY (ARIPIPRAZOLE) (C - Product used for unknown indication - n/a - [n/a] - 10mg - Unknown), XARELTO (RIVAROXABAN) (C - Product used for unknown indication - n/a - [n/a] - 20mg - Unknown), BUMETANIDE (C - Product used for unknown indication - n/a - [n/a] - 1mg - n/a), BUPRENORPHINE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), BUPRENORPHINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a] - 8mg - Unknown), DILTIAZEM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a] - 60mg - Unknown), LEVOTHYRONINE, LEVOTHYRONINE SODIUM (C - Product used for unknown indication - n/a - [n/a] - 200ug - Unknown), NICOBALAMIN (C - Product used for unknown indication - n/a - [n/a] - Unknown), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a] - 100mg - Unknown), MIDODRINE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), VITAMINS NOS (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	ICSR
EU-EC-1008255617	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008256943	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	ALLOPURINOL (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), DOLCHICINE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	ICSR
EU-EC-1008257196	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Exposure to SARS-CoV-2 (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	JARDIANCE (EMPAGLIFLOZIN) (C - Diabetes mellitus - n/a - [n/a] - n/a - Unknown), MELATONIN (MELATONIN) (C - Product used for unknown indication - n/a -), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a -), ALDOXIA, DIETHYLENE GLYCOL MONOETHYL ETHER, MAGNESIUM STEARATE, WOOL ALCOHOLS, CETYL ACETATE, SODIUM DIHYDROGENATE, ZEIN MAYS (C - Immunodeficiency - n/a - n/a - Unknown), ASCORBIC ACID (C - Immunodeficiency - n/a - [n/a] - n/a - Unknown), BUDESONIDE, FORMOTEROL, FLUMARATE DIHYDRATE, FORMOTEROL, FLUMARATE, BUDESONIDE (C - Asthma - n/a - [n/a] - n/a - Unknown), FORMOTEROL, FLUMARATE DIHYDRATE (C - Asthma - n/a -), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BFI (C - Diabetes mellitus - n/a - [n/a] - n/a - Unknown), QUERCETIN (C - Immunodeficiency - n/a -), SALBUTAMOL, SALBUTAMOL SULFATE (C - Asthma - n/a -), ZINC (C - Immunodeficiency - n/a - [n/a] - n/a - Unknown)	ICSR
EU-EC-1008257474	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008257486	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	CLOPIDOGREL, HYDROGEN SULFATE (CLOPIDOGREL, HYDROGEN SULFATE) (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), SITACUPRIN (SITACUPRIN) (C - Product used for unknown indication - n/a - [n/a] - 100mg - Unknown), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a] - Unknown), ASCORBIC ACID (C - Product used for unknown indication - n/a - [n/a] - 100mg - n/a), ATORVASTATIN (C - Product used for unknown indication - n/a - [n/a] - 40mg - n/a), CALCIUM CARBONATE (C - Product used for unknown indication - n/a - [n/a] - 800mg - n/a), CARVEDILOL (C - Product used for unknown indication - n/a - [n/a] - 12.5mg - n/a), FAMOTIDINE (C - Product used for unknown indication - n/a - [n/a] - 20mg - n/a), FERROUS SULFATE (C - Product used for unknown indication - n/a - [n/a] - 325mg - n/a), FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a] - 20mg - n/a), GABAPENTIN (C - Product used for unknown indication - n/a - [n/a] - 300mg - n/a), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BFI (C - Product used for unknown indication - n/a - [n/a] - 500mg - n/a), SALBUTAMOL SULFATE, IPHATRIPIUM BROMIDE (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), SERTRALINE, SERTRALINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a] - 50mg - n/a)	ICSR
EU-EC-1008257763	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008257899	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008258978	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008259251	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008259544	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008261892	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (2d - Fatal - Results in Death), Hypertension (2d - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - n/a - [n/a] - 100mg - Intramuscular)	ROLUFTA 55 MICROGRAMS INHALATION POWDER, PRE-SPINSEB (UMECILINIUM BROMIDE) (C - n/a - n/a - [n/a] - n/a - n/a), XARELTO (RIVAROXABAN) (C - n/a - n/a - [n/a] - n/a - n/a), BISOPROLOL, FLUMARATE (C - n/a - n/a - [n/a] - n/a - n/a), FUROSEMIDE, FUROSEMIDE SODIUM (C - n/a - n/a - [n/a] - n/a - n/a), RAMIPRIL (C - n/a - n/a - [n/a] - n/a - n/a), TERAZOSIN HYDROCHLORIDE DIHYDRATE (C - n/a - n/a - [n/a] - n/a - n/a)	ICSR
EU-EC-1008263448	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - immunisation - n/a - [n/a] - n/a - Intramuscular)	Not reported	ICSR
EU-EC-1008263949	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Arrhythmia 1d - Fatal - Results in Death, Cardiac failure congestive 1(d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Fall 1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008264191	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Dyspnoea (25d - Unknown - Caused/Prolonged Hospitalisation), Hip fracture (n/a - Fatal - Results in Death), Pneumonia bacterial (n/a - Fatal - Results in Death), Poor peripheral circulation (25d - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008264304	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008264322	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1440min - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	BACLOFEN (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), DUCPAPAN (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), HYDROXYMETHYLOXONE (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), MELoxicAM (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), EMEPRAZOLE (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a] - 81mg - n/a), ATORVASTATIN (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), CEFTAZIDIME, CEFTAZIDIME PENTAHYDRATE, CEFTAZIDIME PENTAHYDRATE STERILE BUFFERED (C - Product used for unknown indication - n/a - [n/a] - 1500mg - n/a), EUFECTIN ALFA (C - Product used for unknown indication - n/a - [n/a] - 16000DP - n/a), FLUCONAZOLE (C - Product used for unknown indication - n/a - [n/a] - 100mg - n/a), FUOXETRIN (C - Product used for unknown indication - n/a - [n/a] - 2500L - n/a), MINERAL VITAMINS NOS (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), POTASSIUM CHLORIDE (C - Product used for unknown indication - n/a - [n/a] - 20meq - n/a), VANCOMYCIN, VANCOMYCIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a] - 1500mg - n/a)	ICSR
EU-EC-1008264328	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-1008264393	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (9d - Fatal - Results in Death), Diarrhoea (9d - Unknown - Other Medically Important Condition), Hypertension (9d - Unknown - Other Medically Important Condition), Hypoglycaemia (9d - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10082641033	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10082641167	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10082641511	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Confusional state (205 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dyspepsia (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mental impairment (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Septic (20d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	METHOTREXATE (METHOTREXATE) (C - n/a - n/a -), ALENDRONATE SODIUM, ALENDRONATE SODIUM TRIHYDRATE, ALENDRONIC ACID (C - n/a - n/a -), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - n/a - n/a -), BISOPROLOL, BISOPROLOL HYDROCHLORIDE (C - n/a - n/a -), FOLIC ACID (C - n/a - n/a -), LANTANUM (C - n/a - n/a -), NAPROXEN, NAPROXEN SODIUM (C - n/a - n/a -), EMEPRAZOLE (C - n/a - n/a -), ELIQUIS (APIXIBAN) (C - n/a - n/a -), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - n/a - n/a -), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - n/a - n/a -), FUROSEMIDE (C - n/a - n/a -), GABAPENTIN (C - n/a - n/a -), LISINAPRIL, LISINAPRIL DIHYDRATE (C - n/a - n/a -), POTASSIUM CHLORIDE (C - n/a - n/a -)	ICSR
EU-EC-10082641541	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Confusional state (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Lethargy (n/a - Unknown -), Memory impairment (n/a - Unknown -), Nightmare (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10082642238	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10082642607	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	ELIQUIS (APIXIBAN) (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	ICSR
EU-EC-10082642548	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Unknown -), Death (1d - Fatal - Results in Death), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10082642712	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10082642759	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - [1DF] - Intramuscular)	EMEPRAZOLE, EMEPRAZOLE MAGNESIUM (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), VITAMINS NOS (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	ICSR
EU-EC-10082642760	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Bowel movement irregularity (4d - Unknown -), Death (1d - Fatal - Results in Death), Decreased appetite (4d - Unknown -), Defecation disorder (4d - Unknown -), Dyspnoea (4d - Unknown -), Nausea (4d - Unknown -), Pain (4d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not		

EU Local Number	EV Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Age Group	Sex	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspecting/Related Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
EU-EC-100824343	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Diarrhoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Pain (n/a - Unknown -), Paraesthesia (n/a - Unknown -), Unresponsive to stimuli (n/a - Unknown -) Death (44 - Fatal - Results in Death), Decreased appetite (4 - Fatal - Results in Death), Dyspepsia (44 - Fatal - Results in Death), Fatigue (44 - Fatal - Results in Death), Myocardial infarction (44 - Fatal - Results in Death), Nausea (44 - Fatal - Results in Death), Pain (44 - Fatal - Results in Death), Pyrexia (44 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	METHOCARBAMOL (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a]), PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), BUCFALFATE (C - Product used for unknown indication - n/a - [n/a - 1g - n/a])	CS
EU-EC-100824345	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1440min - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100824370	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (17d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100824418	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death), Feeding tube used (1d - Fatal - Results in Death), General physical health deterioration (1d - Fatal - Results in Death), Hypophagia (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	ATORVASTATIN (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), FAMOTIDINE, FAMOTIDINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), FLUCLOXATINE, FLUCLOXATINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MEGESTROL ACETATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PENTOXIFYLLINE (C - Product used for unknown indication - n/a - [n/a - 800mg - n/a]), QUETIAPINE, QUETIAPINE FUMARATE (C - Product used for unknown indication - n/a - [n/a - 200mg - n/a]), TERAZEPAM (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a])	CS
EU-EC-100824418	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100824273	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Asthma (n/a - Unknown -), Death (1d - Fatal - Results in Death), Eye movement disorder (n/a - Unknown -), Feeling abnormal (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - Intramuscular)	CINACALCET (IONACALCET) (C - Product used for unknown indication - n/a - [n/a - 30mg - Unknown]), PANTOPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE (C - Dyspepsia - n/a - [n/a - 20mg - Unknown]), SEVELAMER (SEVELAMER, SEVELAMER CARBONATE) (C - Product used for unknown indication - n/a - [n/a - 2400mg - Unknown]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MESILATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), CARVEDILOL (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), TERAZOSIN, TERAZOSIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 2mg - Unknown])	CS
EU-EC-100824475	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Chest pain (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Gastroenteropancreatic disease (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	BEPOTASTINE BESILATE (C - Product used for unknown indication - n/a -), BETAXOLOL, BETAXOLOL HYDROCHLORIDE (C - Product used for unknown indication - n/a -), BIRMONDINE, BIRMONDINE TARTRATE (C - Product used for unknown indication - n/a -), NETOBIPIBEN (C - Product used for unknown indication - n/a -), LAFANODINOL, NETOBIPIBEN MESILATE (C - Product used for unknown indication - n/a -), PROPYLENE GLYCOL, MACROGOL, PROPYLENE GLYCOL, MACROGOL 400 (C - Product used for unknown indication - n/a -), PROPYLENE GLYCOL (C - Product used for unknown indication - n/a -), TITROPPIUM, TITROPPIUM BROMIDE MONOHYDRATE (C - Product used for unknown indication - n/a -)	CS
EU-EC-100824476	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100824513	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - n/a - n/a - [n/a - n/a - n/a]), PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), ACETYLSALICYLIC ACID (C - n/a - n/a - [n/a - n/a - n/a]), DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE (C - n/a - n/a - [n/a - n/a - n/a]), GABAPENTIN (C - n/a - n/a - [n/a - n/a - n/a]), BIPRATROPILUM (C - n/a - n/a - [n/a - n/a - n/a]), OLMESARTAN, OLMESARTAN MEDOXIMIL (C - n/a - n/a - [n/a - n/a - n/a]), ROSUVASTATIN, ROSUVASTATIN CALCIUM (C - n/a - n/a - [n/a - n/a - n/a]), UBIQUINONE (C - n/a - n/a - [n/a - n/a - n/a])	CS
EU-EC-100824516	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female No Chest pain (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Headache (n/a - Unknown -), Nausea (n/a - Unknown -), Pain (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100824521	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100824619	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	EFEPHRIINE (C - Asthma - n/a - [n/a - n/a - Unknown])	CS
EU-EC-100824621	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Chronic obstructive pulmonary disease (2d - Unknown -), Condition aggravated (2d - Unknown -), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100824642	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Brain ischaemia (1d - Fatal - Results in Death), Cerebral haemorrhage (1d - Fatal - Results in Death), Cerebral mass effect (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Neurological symptom (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - Intramuscular)	ELIGUS (FIVABAN) (C - Product used for unknown indication - n/a -), AMODARONE, AMODARONE HYDROCHLORIDE (C - Product used for unknown indication - n/a -), DIAZEPAM (C - Product used for unknown indication - n/a -), HYDROCODONE BITARTRATE, PARACETAMOL (C - Product used for unknown indication - n/a -), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Product used for unknown indication - n/a -), LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a -), PARACETAMOL (C - Product used for unknown indication - n/a -), PRIMIDONE (C - Product used for unknown indication - n/a -), TRIMETHOPRIM (C - Product used for unknown indication - n/a -), BRINACE (PILBODOL) (C - Product used for unknown indication - Not applicable -), HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - Not applicable -), LITHIUM (C - Product used for unknown indication - Not applicable -), LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - Not applicable -), VITAMIN D (C - Product used for unknown indication - Not applicable -)	CS
EU-EC-100824644	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Abdominal distension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Dehydration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100824647	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Asthma (n/a - Unknown - Caused/Prolonged Hospitalisation), Child rash (Unknown -), Death (n/a - Fatal - Results in Death), Dry throat (n/a - Unknown -), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Eye movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown -), Irritability (n/a - Unknown - Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown -), Pulver (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Unknown - Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100824647	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male No Tumor (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100824687	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Hypertension (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - Intramuscular)	ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - 81mg - Unknown]), AMLODIPINE BESILATE (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), CARVEDILOL (C - Product used for unknown indication - n/a - [n/a - 25mg - Unknown]), DOLICALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - Product used for unknown indication - n/a - [n/a - Unknown]), DOXYBUTYRIN (DOXYBUTYRIN, DOXYBUTYRIN HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - Unknown]), PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CALCIUM CARBONATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CEFALEXIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), COLICALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DOMEPEZOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LACTOBACILLUS ACIDOPHILUS (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CS
EU-EC-100824689	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100825293	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100825295	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100825294	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100826245	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	HYDROCHLOROTHIAZIDE, AMLODIPINE BESILATE, OLMESARTAN, OLMESARTAN MEDOXIMIL, AMLODIPINE, HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - Dose not changed - [n/a - n/a - n/a])	CS
EU-EC-100826281	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Mental status changes (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100826355	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female No Death (1d - Fatal - Results in Death), Malaise (1d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100826349	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Cardiac failure congestive (n/a - Fatal - Results in Death), Condition aggravated (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Oedema (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Tachypnoea (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	NCURSE ELLIPTA (LAMECLONIDUM BROMIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FLUTICASON (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FUROSEMIDE, POTASSIUM CHLORIDE (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), GABAPENTIN (C - Product used for unknown indication - n/a - [n/a - 1500mg - Unknown]), LOSOPRIL, LOSOPRIL BIPHENATE (C - n/a - n/a - [n/a - 20mg - Unknown]), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF (C - Product used for unknown indication - n/a - [n/a - 1000mg - Unknown]), NARXEDON (C - Product used for unknown indication - n/a - [n/a - 1000mg - Unknown]), POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), SALMETEROL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CS
EU-EC-100826357	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100826374	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Asthma (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Dyspnoea (1d - Fatal - Results in Death), Oxygen saturation decreased (1d - Fatal - Results in Death), Productive cough (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100826278	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100826752	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death), Dyspnoea (3d - Fatal - Results in Death), Pyrexia (3d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100826818	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CS
EU-EC-100826849	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100826875	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100826912	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100826961	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS
EU-EC-100826974	06/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male No Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CS

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group	Patent Age Group (at report)	Patent Sex	Patent Chrt Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Involved Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
										Pain in extremity (1d - Fatal - Results in Death), Pyrexia (2d - Fatal - Results in Death), Rash pruritic (2d - Fatal - Results in Death)		METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MOMETASONE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ELIQUIS [APIXIBAN] (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), NORPHINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 1300mg - n/a]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [SPRONOLACTON] (C - Product used for unknown indication - n/a - [n/a - 12.5mg - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), [CHLORPHENIRAMINE MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE, BUPROPION, BUPROPION (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIPHYRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PROCHLORPERAZINE, PROCHLORPERAZINE MALEATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SPRONOLACTON] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TENOCIPRIL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BRIVARACETAM [BRIVARACETAM] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [LAMOTRIGINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral])		
EU-EC-1000203940	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Back pain (4d - Unknown -), Cordian agitated (4d - Unknown -), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular] - More in ICSR)		ICSR	
EU-EC-1000201172	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Mental status changes (2d - Fatal - Results in Death, CausedProlonged Hospitalisation), Thrombocytopenia (2d - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000201499	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	SPIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000201548	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Obesity (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000201674	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000201965	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000202137	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000202169	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000202199	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000202220	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000170303	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Renal pain (n/a - Unknown -)	SPIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	IRRESARTAN 75 MG, TABLET (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), PREGABALIN [PREGABALIN] (C - n/a - n/a - [n/a - n/a - n/a]), SEVELAMER HYDROCHLORIDE 800MG TABLET, FILM-COATED TABLET (C - n/a - n/a - [n/a - n/a - n/a]), SILDENAFIL CITRATE [SILDENAFIL CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [INSULIN, INSULIN HUMAN] (C - n/a - n/a - [n/a - n/a - n/a]), METOPROLOL TARTRATE (C - n/a - n/a - [n/a - n/a - n/a]), [NIFEDIPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Hyperlipidemia - n/a - [n/a - 20mg - n/a]), [COLECALCIFEROL] (C - Product used for unknown indication - n/a - [n/a - 2000IU - n/a]), [FAMCICLOVIR] (C - Product used for unknown indication - n/a - [n/a - 250mg - n/a]), [GLUCOSAMINE HYDROCHLORIDE, CHONDROITIN SULFATE SODIUM, SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [MELCOXAM] (C - Product used for unknown indication - n/a - [n/a - 7.5mg - n/a])	ICSR	
EU-EC-1000172916	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Headache (n/a - Unknown -), Respiration abnormal (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000173134	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000173171	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute respiratory failure (2d - Fatal - Results in Death, CausedProlonged Hospitalisation), Blood glucose increased (2d - Fatal - Results in Death, CausedProlonged Hospitalisation), Cardiac failure acute (2d - Fatal - Results in Death, CausedProlonged Hospitalisation), Death (1d - Fatal - Results in Death, CausedProlonged Hospitalisation), Metabolic encephalopathy (2d - Fatal - Results in Death, CausedProlonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000173206	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Acute abdomen (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Gastrostomy (n/a - Fatal - Results in Death), Hypoglycaemia (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	APIXIBAN [APIXIBAN] (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), INSULIN LISPRO [INSULIN LISPRO] (C - Product used for unknown indication - n/a -), [ATENOLOL, ATENOLOL BPF] (C - Product used for unknown indication - n/a - [n/a - 75mg - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 80mg - n/a]), [COLESTYRAMINE] (C - Product used for unknown indication - n/a - [n/a - 4g - n/a]), [ESICATOPRAM, ESICATOPRAM OXALATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), FERROUS SULFATE (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a]), [FLUCONAZOLE] (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), FUROSEMIDE, FUROSEMIDE SODIUM (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 650mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000173994	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000174060	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (2d - Fatal - Results in Death), Multiple organ dysfunction syndrome (2d - Fatal - Results in Death), Pulse absent (2d - Fatal - Results in Death), Pulseless electrical activity (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	METHOTREXATE [METHOTREXATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ATENOLOL, ATENOLOL BPF] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [BENZONATONE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [FAMOTIDINE, FAMOTIDINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SABAFENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [HYDROXYCHLOROQUINE SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LANOPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [DIPYRIDONE, DIPHENIDRAMINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TIOPROPRIL, TIOPROPRIL CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000174251	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000174421	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	ANDRO ELLIPTA [UMECLOINUM BROMIDE, VILANTEROL, UMECLOINUM BROMIDE, VILANTEROL, TRIFENATE, UMECLOINUM, VILANTEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), INTELENCE [ETRAVIRINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MIRAPROIN [MIRAPROIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [DIPYRIDONE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SABAFENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ROBUSVASTATIN, ROBUSVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000174581	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Malaise (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	[CETIRIZINE, CETIRIZINE HYDROCHLORIDE] (C - Product used for unknown indication - Unknown -), [CITALOPRAM, CITALOPRAM HYDROBROMIDE] (C - Product used for unknown indication - Unknown -), [MEMANTINE, MEMANTINE HYDROCHLORIDE] (C - Product used for unknown indication - Unknown -), [TEMAZEPAM] (C - Product used for unknown indication - Unknown -)	ICSR	
EU-EC-1000174692	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000175150	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	APIXIBAN [APIXIBAN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [OMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR	
EU-EC-1000175359	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000175351	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000175353	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Atrial fibrillation (7d - Fatal - Results in Death), Death (7d - Fatal - Results in Death), Influenza like illness (7d - Fatal - Results in Death), Pain in extremity (7d - Fatal - Results in Death), Syncope (7d - Fatal - Results in Death, Other Medically Important Condition), Tumor (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	[ALPHA-TOCOPHEROL] (C - Product used for unknown indication - Not applicable - [n/a - n/a - n/a]), [CELECOXIB] (C - Product used for unknown indication - Not applicable - [n/a - 200mg - n/a]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - Not applicable - [n/a - n/a - n/a]), [MOXIFLOXACIN] (C - Product used for unknown indication - n/a - [n/a - 400 - n/a]), [OMEPRAZOLE] (C - Product used for unknown indication - Not applicable - [n/a - n/a - n/a]), [PHENAZONE, PHENAZONE, PHENAZONE] (C - Product used for unknown indication - Unknown -), [VITAMIN E] (C - Product used for unknown indication - Unknown -)	ICSR	
EU-EC-1000175607	02/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death), Vomiting (n/a - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])	ATORVASTATIN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ASPIRIN, ASPIRIN] (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a]), [DIPYRIDONE] (C - Product used for unknown indication - n/a - [n/a - 125mg - n/a]), [DIPHENHYDRAMINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 112µg - n/a]), [MEGESTROL, ACETATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 4000mg - n/a]), [NIVONAN] [CANAGLIFLOZIN] (C - Type 2 diabetes mellitus - Not applicable - [n/a - 300mg - Oral]), [JANUMET, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE MONOHYDRATE] (C - Type 2 diabetes mellitus - Not applicable - [n/a - 1000mg - Oral]), [PLAVIX] [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (C - Product used for unknown indication - Not applicable - [n/a - 75mg - Oral]), [AMLODIPINE BESILATE, PERINDOPRIL, ARGININE, AMLODIPINE, PERINDOPRIL] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), [CHONDROITIN SULFATE, CHONDROITIN SULFATE SODIUM] (C - Product used for unknown indication - Not applicable - [n/a - 800mg - Oral])	ICSR	
EU-EC-1000181724	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebellar stroke (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	SPIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000181969	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Malaise (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000182014	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000182675	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - n/a - [n/a - 5mL - Intramuscular])		ICSR	
EU-EC-1000183017	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000183029	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Impaired work ability (n/a - Unknown -), Malaise (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000183472	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000184016	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000184044	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000184099	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 100µg - Intramuscular])		ICSR	
EU-EC-1000184428														

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspected/Reported Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form	
EU-EC-1000165104	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	ASCORBIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), COLECALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), CYANOCOBALAMIN FOLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ROSEHIP SEED OIL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000165163	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000165173	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cough (n/a - Unknown - Life Threatening), Death (n/a - Fatal - Results in Death), Dysgeusia (n/a - Unknown - Life Threatening), Exposure to SARS-CoV-2 (n/a - Unknown - Life Threatening), Fruiting abnormal (n/a - Unknown - Life Threatening), Gastrointestinal tract irritation (n/a - Unknown - Life Threatening), Headache (n/a - Unknown - Life Threatening), Malaise (n/a - Unknown - Life Threatening), Micturition urgency (n/a - Unknown - Life Threatening), Pain (n/a - Unknown - Life Threatening), Poliuria (n/a - Unknown - Life Threatening), Resuscitation (n/a - Unknown - Life Threatening), SARS-CoV-2 test negative (n/a - Unknown - Life Threatening), Somnolence (n/a - Unknown - Life Threatening), Syncope (n/a - Unknown - Life Threatening), Upper respiratory tract infection (n/a - Unknown - Life Threatening)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	HYDROCHLOROTHIAZIDE, TRIMETHOPRIM (C - n/a - n/a -), LISINAPRIL, LISINAPRIL DIHYDRATE (C - n/a - n/a -)	ICSR	
EU-EC-1000165204	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	METOPROLOL, SUCCINATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), OMEPRAZOLE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PREDNISOLONE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR	
EU-EC-1000165509	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (4d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000165609	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	CANNABIDIOL, CANNABIDIOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ATELENOL, ATELENOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), AZELASTINE, AZELASTINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), CASBIA (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRHYDRATE, ESOMEPRAZOLE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), HALOPERIDOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), HYDRALAZINE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), HYDROCODONE BITARTRATE, PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), HYDROXYMINE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LEVOSIBUTAMOL, TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), MORPHINE, MORPHINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), NIFEDIPINE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), OXYSERIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), TURMERIC (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), UMECIDINIUM, VILANTEROL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), VITAMIN D3 (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-1000165939	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000166272	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cardiac arrest (1d - Unknown - Life Threatening), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000166369	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chest pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulse absent (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000166382	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Fatigue (2d - Unknown -), Myalgia (2d - Unknown -)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	BRIVACTAM, BRIVACTAM (C - Product used for unknown indication - Dose not changed - [n/a - 100mg - Oral]), PANTOZOL, CONTROL (PANTOZOL) (C - Product used for unknown indication - Dose not changed - [n/a - 20mg - Oral]), EPROSARTAN MESLATE, HYDROCHLOROTHIAZIDE, EPROSARTAN, HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - Dose not changed - [n/a - 600mg - Oral]), LAMOTRIGINE (C - Product used for unknown indication - Dose not changed - [n/a - n/a - Oral]), ZOLPIDEM, ZOLPIDEM TARTRATE (C - Product used for unknown indication - Dose not changed - [n/a - n/a - Oral])	ICSR	
EU-EC-1000166673	01/04/2021	Spontaneous	Not Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Lethargy (n/a - Unknown -), Respiration abnormal (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	FERROUS SULFATE (C - Product used for unknown indication - n/a - [n/a - 325mg - n/a]), INSULIN HUMAN, INSULIN HUMAN ZINC, ISOPHANE INSULIN, INSULIN HUMAN (C - Diabetes mellitus - n/a - [n/a - 200DP] - n/a), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Hypertension - n/a - [n/a - 2.5mg - n/a]), SIBASTATIN (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a])	ICSR	
EU-EC-1000166778	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000166816	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000167139	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Eye contusion (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000167175	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000167208	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (2d - Fatal - Results in Death), Malaise (2d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000167224	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000167291	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	ELIQUIS (APRABAN) (C - n/a - n/a - [n/a - n/a - Unknown]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESLATE (C - n/a - n/a - [n/a - n/a - Unknown]), CARVEDILOL (C - n/a - n/a - [n/a - n/a - Unknown]), ENALAPRIL MALEATE (C - n/a - n/a - [n/a - n/a - Unknown]), OMEPRAZOLE, OMEPRAZOLE MAGNESIUM (C - n/a - n/a - [n/a - n/a - Unknown]), PHACETAMIN (C - n/a - n/a - [n/a - n/a - Unknown])	ICSR	
EU-EC-1000167467	01/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Bronchitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000144267	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (0d - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - n/a - [n/a - 5mL - Intramuscular])	SEVELAMER (SEVELAMER, SEVELAMER CARBONATE) (C - n/a - n/a - [n/a - n/a - n/a]), BISOPROLOL FUMARATE (C - n/a - n/a - [n/a - n/a - n/a]), CEFTAZIDIME (C - n/a - n/a - [n/a - n/a - n/a]), FUROSEMIDE (C - n/a - n/a - [n/a - n/a - n/a]), METHYLPREDNISOLONE, METHYLPREDNISOLONE ACETATE, METHYLPREDNISOLONE SODIUM HEMISUCCINATE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000148051	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000149399	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000152645	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000153345	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	XARELTO (RIVAROXABAN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), COLECALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), OMEPRAZOLE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PROPRANLOL, PROPRANLOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SPRONOLACTONE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SUCRALFATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000154089	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000154216	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000155629	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000155884	31/03/2021	Spontaneous	Not Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Gastric cancer stage IV (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000156200	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000156309	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000156349	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	ICSR	
EU-EC-1000156459	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000156458	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown -), Respiratory distress (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000156586	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	ACETYLSALICYLIC ACID, ASPIRIN (C - n/a - n/a - [n/a - n/a - n/a]), ALLIUM SATIVUM (C - n/a - n/a -), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESLATE (C - n/a - n/a -), ATORVASTATIN (C - n/a - n/a -), BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE (C - n/a - n/a -), ESCITALOPRAM, ESCITALOPRAM OXALATE (C - n/a - n/a -), HYDROCODONE BITARTRATE, PARACETAMOL (C - n/a - n/a -), IBUPROFEN (C - n/a - n/a -), NONPHELEPHANT, NONPHELEPHANT SODIUM (C - n/a - n/a -), SIBASTATIN, SIBASTATIN SULFATE (C - n/a - n/a -), TAMSOLOXIN HYDROCHLORIDE (C - n/a - n/a -)	Not reported	ICSR
EU-EC-1000156967	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Faeces discoloured (n/a - Fatal - Results in Death), Fat (n/a - Fatal - Results in Death), Hypoxia (1d - Fatal - Results in Death), Mental status changes (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death), Pulse absent (1d - Fatal - Results in Death), Terminal state (1d - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	ICSR	
EU-EC-1000156472	30/03/2021	Spontaneous	Not Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Dizziness (n/a - Not Recovered/Not Resolved -), Loss of consciousness (n/a - Not Recovered/Not Resolved -), Somnolence (n/a - Not Recovered/Not Resolved -)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000156879	30/03/2021	Spontaneous	Not Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved -), Hypertonia (n/a - Not Recovered/Not Resolved -), Hypothermia (n/a - Not Recovered/Not Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular - More in ICSR)	Not reported	ICSR	
EU-EC-1000157254	30/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	IRON (IRON) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ALOPURINOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LIOTHYROXINE, LIOTHYROXINE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), OMEPRAZOLE, OMEPRAZOLE MAGNESIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000157882	30/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chills (n/a - Unknown -), Death (1d - Fatal - Results in Death), Fatigue (n/a - Unknown -), Myalgia (n/a - Unknown -), Nausea (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	SALBUTAMOL SULFATE, (PRATROPIUM BROMIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - 8mg - Unknown]), LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - 2mg - Unknown]), METOPROLOL, SUCCINATE (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown])	ICSR	
EU-EC-1000158494	30/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-02441			

EU Local Number	EV Entry Review Date	Report Type	Primary Source Qualification	Primary Source Regulatory Purpose	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Identified Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
										Hypertonia (N/A - Fatal - Results in Death), Myocardial infarction (N/A - Fatal - Results in Death, Other Medically Important Condition), Pain (N/A - Fatal - Results in Death), Pain in extremity (N/A - Fatal - Results in Death)				
EU-EC-1000812970	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Adherens (N/A - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (N/A - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Endotracheal intubation (N/A - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Painless electrical activity (N/A - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	ACETYLSALICYLIC ACID (C - Product used for unknown indication - Drug withdrawn - [N/A - n/a - n/a]), ATORVASTATIN (C - Product used for unknown indication - Drug withdrawn - [N/A - 40mg - Oral]), BISACODYL (C - Product used for unknown indication - n/a - [N/A - 5mg - Oral]), COLICALCIFEROL (C - Product used for unknown indication - n/a - [N/A - n/a - Oral]), METHOCARBAMOL (C - Product used for unknown indication - Drug withdrawn - [N/A - 100mg - Oral]), METOPROLOL SUCCINATE (C - Product used for unknown indication - n/a - [N/A - 25mg - Oral]), PARACETAMOL (C - Product used for unknown indication - n/a - [N/A - 3g - Oral])	ICSR	
EU-EC-1000812978	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Confusional state (N/A - Not Recovered/Not Resolved -), Death (1d - Fatal - Results in Death), Dementia (N/A - Not Recovered/Not Resolved - Other Medically Important Condition), Diet refusal (N/A - Not Recovered/Not Resolved -), Renal failure (N/A - Not Recovered/Not Resolved - Other Medically Important Condition), Restlessness (N/A - Not Recovered/Not Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000812978	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardio-respiratory arrest (N/A - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Dyspnoea (N/A - Unknown - Caused/Prolonged Hospitalisation), Fat (N/A - Unknown - Caused/Prolonged Hospitalisation), Hypertension (N/A - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (N/A - Unknown - Caused/Prolonged Hospitalisation), Musculoskeletal stiffness (N/A - Unknown - Caused/Prolonged Hospitalisation), Pain (N/A - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (N/A - Unknown - Caused/Prolonged Hospitalisation), Respiration abnormal (N/A - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (N/A - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000812980	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Unresponsive to stimuli (N/A - Unknown - Caused/Prolonged Hospitalisation), Conversion disorder (S - Unknown -), Death (N/A - Fatal - Results in Death), Dysphagia (S - Unknown -), Fatigue (S - Unknown -), Pyrexia (S - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), ALPRAZOLAM (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), ASCORBIC ACID (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), COLICALCIFEROL (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), CYANOCOBALAMIN (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), FERROUS SULFATE (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), LEVOTHYRONINE LEVOTHYRONINE SODIUM (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), MIRTAZAPINE (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), NICOTINIC ACID (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), NITROGLYCERIN (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), DMEPRAZOLE (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), RISPERIDONE (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), SOLIDAGO VIRGAUREA (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), THYMUS VULGARIS (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), VACCINIUM MACROCARPON (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), ZEA MAYS (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown])	ICSR	
EU-EC-1000808619	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (N/A - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000808604	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Decreased appetite (N/A - Unknown -), Dry mouth (N/A - Unknown -), Dyspnoea (1d - Unknown -), Fatigue (N/A - Unknown -), Hypertension (N/A - Unknown -), Pain (N/A - Unknown -), Pyrexia (N/A - Unknown -), Unresponsive to stimuli (1d - Unknown - Other Medically Important Condition), Wheezing (N/A - Unknown -)	SPIREVA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	GALVUS (D,L)GLUTAMINE (C - Product used for unknown indication - n/a - [N/A - 50mg - n/a]), LEVETIRACETAM ACTAVIS (LEVETIRACETAM) (C - Product used for unknown indication - n/a - [N/A - 500mg - n/a]), SIFROL (PRAMPEXOLE DIIHYDROCHLORIDE MONOHYDRATE) (C - Product used for unknown indication - n/a - [N/A - 25mg - n/a]), ESCITALOPRAM (C - Product used for unknown indication - n/a - [N/A - 10mg - n/a]), HALOPERIDOL DECANOATE (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), MACROGOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350 (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), METFORMIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [N/A - 1000mg - n/a]), NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (DIAZEPAM (C - Product used for unknown indication - n/a - [N/A - 15mg - n/a]), (TORASEMIDE (C - Product used for unknown indication - n/a - [N/A - 10mg - n/a])	ICSR	
EU-EC-1000808624	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Pyrexia (N/A - Unknown - Caused/Prolonged Hospitalisation)	SPIREVA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000808610	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (N/A - Fatal - Results in Death)	SPIREVA (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000808615	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	COVID-19 (N/A - Unknown -), COVID-19 pneumonia (Sd - Unknown -), Cough (N/A - Unknown -), Death (N/A - Fatal - Results in Death), Dyspnoea (N/A - Unknown -), Emotional distress (N/A - Unknown -), Malaise (N/A - Unknown -), Pyrexia (N/A - Unknown -), Rales (N/A - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	BUPROFEN (BUPROFEN, BUPROFEN SODIUM) (C - Product used for unknown indication - n/a - [N/A - 400mg - Unknown]), TICVAY (DOLUETRAVIR) (C - Product used for unknown indication - n/a - [N/A - 100mg - Unknown]), AMOXICILLIN SODIUM, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID, AMOXICILLIN, POTASSIUM CLAVULANATE (S - Product used for unknown indication - n/a - [N/A - 125mg - Unknown]), BENZONATATE (C - Cough - n/a - [N/A - n/a - Unknown]), CETRIZINE DIIHYDROCHLORIDE (C - Product used for unknown indication - n/a - [N/A - 10mg - Unknown]), CHLORHEXIDINE GLUCONATE (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), DICLOFENAC, DICLOFENAC POTASSIUM, DICLOFENAC SODIUM (C - Product used for unknown indication - n/a - [N/A - n/a - Topical]), FLUTICASON PROPIONATE (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), LAMIVUDINE, TENOFOVIR DISOPROXIL FUMARATE (C - Product used for unknown indication - n/a - [N/A - 300mg - Unknown])	ICSR	
EU-EC-1000808607	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Pyrexia (1d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular] - More in ICSR)	Not reported	ICSR	
EU-EC-1000808648	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Diet refusal (21d - Unknown -), Refusal of treatment by patient (N/A - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000808627	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Decreased appetite (N/A - Unknown -), Fatigue (N/A - Unknown -), Headache (N/A - Unknown -), Insomnia (N/A - Unknown -), Lethargy (N/A - Unknown -), Malaise (N/A - Unknown -), Nicturia (N/A - Unknown -), Polyuria (N/A - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000808610	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	HYDROCHLOROTHIAZIDE, TRAMETRENE (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), DMEPRAZOLE (C - Product used for unknown indication - n/a - [N/A - n/a - n/a])	ICSR	
EU-EC-1000808616	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	COLICALCIFEROL, CALCIUM CARBONATE (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), FLUXETINE, FLUXETINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [N/A - 20mg - n/a]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), MAGNESIUM, ALPHA-TOCOPIEROL (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), POTASSIUM CHLORIDE (C - Product used for unknown indication - n/a - [N/A - 40meq - n/a]), PRAVASTATIN, PRAVASTATIN SODIUM (C - Product used for unknown indication - n/a - [N/A - 40mg - n/a]), TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE (C - Product used for unknown indication - n/a - [N/A - 8mg - n/a])	Not reported	ICSR
EU-EC-1000808626	29/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Fatigue (N/A - Unknown -), Malaise (N/A - Unknown -), Musculoskeletal stiffness (N/A - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular] - More in ICSR)	Not reported	ICSR	
EU-EC-1000808617	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-10008086318	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-10008086287	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	DULOXETINE (DULOXETINE, DULOXETINE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), BUPROFEN (BUPROFEN, BUPROFEN SODIUM) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), ATORVASTATIN (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), CARVEDILOL (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), DABEPENTIN (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), HYDROCODONE BITARTRATE, PARACETAMOL (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), HYDROCODONE BITARTRATE, PARACETAMOL (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), LORATADINE (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), MORFINUM (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), ELIGUR (ELIGURAN) (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), CARVEDILOL (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), (CEFTRIAZONE, CEFTRIAZONE DISODIUM, CEFTRIAZONE DISSOLUBLE SALT, HEMIPHTALANATE, CEFTRIAZONE SODIUM, CEFTRIAZONE, LIDOCANE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), (ENALAPRIL MALEATE) (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), DMEPRAZOLE (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), (PARACETAMOL) (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), (POTASSIUM CHLORIDE) (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), (QUETIAPINE, QUETIAPINE FUMARATE) (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown])	Not reported	ICSR
EU-EC-10008086346	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-10008086354	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	DULOXETINE (DULOXETINE, DULOXETINE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (SABAPENTIN) (C - Product used for unknown indication - n/a - [N/A - 600mg - n/a]), HYDROCHLOROTHIAZIDE, LISINAPRIL (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), DIIYCODONE, OXYCODONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [N/A - n/a - n/a])	Not reported	ICSR
EU-EC-10008086388	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-10008086437	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Epistaxis (N/A - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	ENALAPRIL (ENALAPRIL, ENALAPRIL SODIUM) (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), (CLATHROPHOSPHON) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (CYANOCOBALAMIN) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (ENALAPRIL, ENALAPRIL MALEATE) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (METOPROLOL, METOPROLOL TARTRATE) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (NITROFURANTOIN) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - Product used for unknown indication - n/a - [N/A - n/a - Unknown]), (TAMBULOSIN HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a])	Not reported	ICSR
EU-EC-10008086598	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Chest pain (N/A - Unknown -), Chills (N/A - Unknown -), Death (1d - Fatal - Results in Death), Fatigue (N/A - Unknown -), Headache (N/A - Unknown -), Headache (N/A - Unknown -), Headache (N/A - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	DUPINTEL (DUPINTEL) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (ATENOLOL, ATENOLOL BP) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (FUROSEMIDE) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (LEVOTHYRONINE, LEVOTHYRONINE SODIUM) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (POTASSIUM CHLORIDE) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a])	Not reported	ICSR
EU-EC-10008086407	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-10008086808	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Malaise (1d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-10008086796	29/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (N/A - Fatal - Results in Death), Dyspnoea (3d - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-10008086752	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Brain herniation (N/A - Unknown - Caused/Prolonged Hospitalisation), Central haemorrhage (N/A - Unknown - Caused/Prolonged Hospitalisation), Central mass effect (N/A - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Encephalitis (N/A - Unknown - Caused/Prolonged Hospitalisation), Meningitis (N/A - Unknown - Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (N/A - Unknown - Caused/Prolonged Hospitalisation), Vasogenic cerebral oedema (N/A - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [N/A - 81mg - n/a]), (ALEDRONATE SODIUM, ALEDRONATE SODIUM TRIHYDRATE, ALEDRONIC ACID) (C - Product used for unknown indication - n/a - [N/A - 70mg - n/a]), (HYDROXYCHLOROQUINE SULFATE) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (LEVOTHYRONINE, LEVOTHYRONINE SODIUM) (C - Product used for unknown indication - n/a - [N/A - 100ug - n/a]), (LOSARTAN, LOSARTAN POTASSIUM) (C - Product used for unknown indication - n/a - [N/A - 50mg - n/a]), (MECLOZINE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [N/A - 12.5mg - n/a]), (METOPROLOL SUCCINATE) (C - Product used for unknown indication - n/a - [N/A - 50mg - n/a]), (PARACETAMOL) (C - Product used for unknown indication - n/a - [N/A - 650mg - n/a]), (ROSUVASTATIN, ROSUVASTATIN CALCIUM) (C - Product used for unknown indication - n/a - [N/A - 30mg - n/a]), (VITAMIN D, CALCIUM) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a])	Not reported	ICSR
EU-EC-10008086808	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-10008086296	24/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-10008086290	24/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (N/A - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [N/A - 1(DP) - Intramuscular])	ATORVASTATIN (C - Product used for unknown indication - n/a - [N/A - n/a - n/a]), (DALANTAMINE) (C - Product used for unknown indication - n/a - [N/A - n/a - n/a])	ICSR	

EU Local Number	EY Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Available	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
EU-EC-1000798260	15/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown - More in ICSR))	Not reported	ICSR
EU-EC-1000798260	15/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown - More in ICSR))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown - More in ICSR))	Not reported	ICSR
EU-EC-1000798335	15/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown - More in ICSR))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown - More in ICSR))	Not reported	ICSR
EU-EC-1000798308	15/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown - More in ICSR))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown - More in ICSR))	Not reported	ICSR
EU-EC-1000798526	15/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Elderly	Male	No	Death (1d - Fatal - Results in Death), Dyspnoea (2d - Fatal - Results in Death), Pyrexia (2d - Fatal - Results in Death), Adhemia (n/a - Fatal - Results in Death), Confusional state (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown - More in ICSR))	Not reported	ICSR
EU-EC-1000798732	17/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Pyrexia (2d - Fatal - Results in Death), Adhemia (n/a - Fatal - Results in Death), Confusional state (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown - More in ICSR))	Not reported	ICSR
EU-EC-1000798875	17/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - Unknown]))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - Unknown]))	Not reported	ICSR
EU-EC-1000798817	17/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	ALENDRONIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ANASTROZOLE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DICLOFENAC SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LISINAPRIL LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LOVASTATIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), NIFEDIPINE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-1000792150	17/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - Unknown]))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - Unknown]))	Not reported	ICSR
EU-EC-1000794487	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - n/a - [n/a - n/a]))	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - n/a - [n/a - n/a]))	Not reported	ICSR
EU-EC-1000794484	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - n/a - [n/a - n/a]))	SPIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - n/a - [n/a - n/a]))	Not reported	ICSR
EU-EC-1000794524	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Malaise (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Unknown - [n/a - 1DF] - Intramuscular))	ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-1000794520	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	Not reported	ICSR
EU-EC-1000794597	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	Not reported	ICSR
EU-EC-1000794714	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	Not reported	ICSR
EU-EC-1000795040	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (17d - Fatal - Results in Death), Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory tract congestion (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	ROTIHOTINE (ROTIHOTINE) (C - Product used for unknown indication - n/a - [n/a - 6mg - n/a]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), AMANITADINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), FLURIDICONE PROPIONATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PIRFENIDONE (C - Product used for unknown indication - n/a - [n/a - 500DF] - n/a), MEFENAMIC ACID (C - Product used for unknown indication - n/a - [n/a - 400mg - n/a]), METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), AREDS (ASCORBIC ACID, TOCOPHERYL ACETATE, ANTOXYFLAVIN, ZEAXANTHIN, ZINC) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), BIOTIN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), COLECALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), DELTALAZEM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), DIPYRIDAMOLE ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SABAPENTIN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), INSULIN, INSULIN HUMANE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), GADANESTRON, GADANESTRON HYDROCHLORIDE, GADANESTRON HYDROCHLORIDE DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SMETICONE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TRIMETHOPRIM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000795148	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -), Hypersomnia (n/a - Unknown -), Somnolence (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 2DF] - n/a))	ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), BIOTIN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), COLECALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), DELTALAZEM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), DIPYRIDAMOLE ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SABAPENTIN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), INSULIN, INSULIN HUMANE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), GADANESTRON, GADANESTRON HYDROCHLORIDE, GADANESTRON HYDROCHLORIDE DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SMETICONE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TRIMETHOPRIM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007952167	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	Not reported	ICSR
EU-EC-10007953444	15/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	Not reported	ICSR
EU-EC-1000795484	15/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), SARS-CoV-2 test positive (5d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	Not reported	ICSR
EU-EC-1000795493	15/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Agueusia (9d - Unknown -), Death (1d - Fatal - Results in Death), Decreased appetite (9d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	Not reported	ICSR
EU-EC-1000795609	15/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Adhemia (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Gait stability (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Dose not changed - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Dose not changed - [n/a - 1DF] - Intramuscular))	Not reported	ICSR
EU-EC-10007958700	15/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Adhemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death), Hypokalaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	XARELTO (RIVAROXABAN) (C - n/a - n/a -), BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE (C - n/a - n/a -), FURSEMIDE (C - n/a - n/a -), LISINAPRIL, LISINAPRIL DIHYDRATE (C - n/a - n/a -), OMEPRAZOLE (C - n/a - n/a -), ROPINIROLE, ROPINIROLE HYDROCHLORIDE (C - n/a - n/a -), SALBUTAMOL, SALBUTAMOL SULFATE (C - n/a - n/a -), SIMVASTATIN (C - n/a - n/a -), SOTALOL, SOTALOL HYDROCHLORIDE (C - n/a - n/a -), TAMBOLOXIN HYDROCHLORIDE (C - n/a - n/a -)	Not reported	ICSR
EU-EC-1000795883	15/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	Not reported	ICSR
EU-EC-1000795887	15/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Aphasia (n/a - Unknown -), Death (1d - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Dyskinesia (n/a - Unknown -), Gait stability (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	ASCORBIC ACID, IRON (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ATENOLOL, ATENOLOL BPF (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), CALCIUM CARBONATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), CYANOCOBALAMIN, FOLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), DOCSUATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ERGOCALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FURSEMIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TAMOXIFEN, TAMOXIFEN CITRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TRAZODONE, TRAZODONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), VITAMIN D3 (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), VITAMINS NOS (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000795928	15/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown))	Not reported	ICSR
EU-EC-1000797075	12/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007970742	12/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Back pain (4d - Unknown -), Death (n/a - Fatal - Results in Death), Diet refusal (4d - Unknown -), Fluid intake reduced (4d - Unknown -), General physical health deterioration (4d - Unknown -), Haematemesis (4d - Unknown -), Nausea (4d - Unknown -), Vomiting (4d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	FENTANYL, FENTANYL, FENTANYL CITRATE (C - Product used for unknown indication - n/a - [n/a - n/a - Transdermal]), BUPROPION, BUPROPION, BUPROPION SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SABAPENTIN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MACRODOL 3300 (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MORPHINE, MORPHINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), OMEPRAZOLE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), DINDANESTRON (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ANKINIS, ESTILGUPITIN, ESTILGUPITIN DIHYDRATE, ESTILGUPITIN PHOSPHATE MONOHYDRATE (C - n/a - n/a -), PLAVIX (CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE) (C - n/a - n/a -), ACETYLSALICYLIC ACID, ASPIRIN BPF (C - n/a - n/a -), ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM (C - n/a - n/a -), ASCORBIC ACID (C - n/a - n/a -), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - n/a - n/a -), CARBIDOPA, LEVODOPA, LEVODOPA, ANHYDROUS CARBIDOPA, LEVODOPA, CARBIDOPA MONOHYDRATE (C - n/a - n/a -), CYANOCOBALAMIN, VITAMIN B12 (C - n/a - n/a -), DOXAZOSIN, DOXAZOSIN MESILATE (C - n/a - n/a -), FINASTERIDE (C - n/a - n/a -), FLUOXETINE, FLUOXETINE HYDROCHLORIDE (C - n/a - n/a -), METOPROLOL, METOPROLOL TARTRATE (C - n/a - n/a -), MONIFLUMATE, TAMBULOXIN HYDROCHLORIDE (C - n/a - n/a -), VITAMIN D3 (C - n/a - n/a -), VITAMINS NOS (C - Product used for unknown indication - n/a - [n/a - 360mL - n/a]), MIMO ACID (C - Product used for unknown indication - n/a - [n/a - 360mL - n/a]), CARBOHYDRATES NOS (C - Product used for unknown indication - n/a - [n/a - 360mL - n/a]), (FATS NOS) (C - Product used for unknown indication - n/a - [n/a - 360mL - n/a]), (FIBRE, DIETARY) (C - Product used for unknown indication - n/a - [n/a - 360mL - n/a]), (MINERALS NOS) (C - Product used for unknown indication - n/a - [n/a - 360mL - n/a]), (VITAMINS NOS) (C - Product used for unknown indication - n/a - [n/a - 360mL - n/a]), ZINC SULFATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ALICURUMOL (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), ATORVASTATIN CALCIUM (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), CALCIOTROL (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), FURSEMIDE (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a]), SABAPENTIN (C - Product used for unknown indication - n/a - [n/a - 2.5mg - n/a]), GLYCERYL TRINITRATE (C - Product used for unknown indication - n/a - [n/a - 60mg - n/a]), ISOSORBIDE (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), WARFARIN, WARFARIN SODIUM (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a])	Not reported	ICSR
EU-EC-1000798077	12/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular))	Not reported	ICSR
EU-EC-1000798430	11/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	No	Death (1d - Fatal - Results in Death), Pneumonia ascription (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414) (S - COVID-19 immunisation - Unknown - [n/a - 1DF] - Intramuscular))	ARXABAN (APIXABAN) (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]), DOCSUATE (C - Product used for unknown indication - n/a - [n/a - 200mg - Oral]), ZINC (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral])	Not reported	ICSR
EU-EC-10007984703	11/03/2021	Spontaneous	Healthcare Professional											

EU Local Number	EY Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Age Group	Sex	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form		
EU-EC-1000795605	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[CALCIOTROL] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [PRATROPIUM SALBUTAMOL] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000795625	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795635	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Unknown)	CARBIDOPA, LEVODOPA [CARBIDOPA, LEVODOPA] (C - Product used for unknown indication - n/a - [n/a] - n/a - Oral), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - Oral), [FINASTERIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [FISH OIL ALPHA TOCOPHEROL] (C - Product used for unknown indication - n/a - [n/a] - n/a - Oral), [FUSICTAMOL] (C - Product used for unknown indication - n/a - [n/a] - 500mg - Oral), [TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - 4mg - Oral), [TMOLINOL TMOLINOL MALEATE] (C - Product used for unknown indication - n/a - [n/a] - 200g - n/a)	CSR
EU-EC-1000795656	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795680	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Hypertension (n/a - Unknown -), Muscle rigidity (n/a - Unknown -), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795719	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795740	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	CSR
EU-EC-1000795754	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000795784	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000795798	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[DOCUATE SODIUM, CASSIA] (C - Product used for unknown indication - n/a - [n/a] - n/a - Oral), [DXYMETAZOLINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Nasal)	CSR
EU-EC-1000795868	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute respiratory distress syndrome (20d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (20d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Respiratory failure (20d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795932	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795974	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795976	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Acute myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Chest pain (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Pericarditis (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795985	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - n/a)	Not reported	CSR
EU-EC-1000795974	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Resisting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795954	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Fatigue (1d - Unknown -), Pain in extremity (1d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795936	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Unresponsive to stimuli (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795948	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795910	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Cardiac failure congestive (2d - Fatal - Results in Death), Cardiomegaly (2d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Feeling hot (2d - Fatal - Results in Death), Hematuria (2d - Fatal - Results in Death), Hypoxia (2d - Fatal - Results in Death), Leukocytosis (2d - Fatal - Results in Death), Pleural effusion (2d - Fatal - Results in Death), Pulmonary edema (2d - Fatal - Results in Death), Pulmonary vascular disorder (2d - Fatal - Results in Death), Renal failure (2d - Fatal - Results in Death), Spinal fracture (2d - Fatal - Results in Death), Urinary tract infection (2d - Fatal - Results in Death), Vomiting (2d - Fatal - Results in Death), White blood cell disorder (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[ALPRAZOLAM] (C - Product used for unknown indication - n/a -), [CAFEOLXIN MONOHYDRATE] (C - Product used for unknown indication - n/a -), [FUROSEMIDE] (C - Product used for unknown indication - n/a -), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a -), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a -), [EMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a -)	CSR
EU-EC-1000795938	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000795923	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[ELIUS (ARXIBAN)] (C - Product used for unknown indication - n/a -), [PROTENEK (NOT AVAILABLE)] (C - Product used for unknown indication - n/a -), [ACETIC ACID] (C - Bladder catheterisation - n/a -), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a -), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a -), [COLESTYRAMINE] (C - Product used for unknown indication - n/a -), [FERROUS SULFATE] (C - Product used for unknown indication - n/a -), [FINASTERIDE] (C - Product used for unknown indication - n/a -), [FLUOXATIN] (C - Product used for unknown indication - n/a -), [LACTOBACILLUS] (C - Product used for unknown indication - n/a -), [LORAZEPAM] (C - Product used for unknown indication - n/a -), [MACRODOL 330] (C - Product used for unknown indication - n/a -), [MAGNESIUM OXIDE] (C - Product used for unknown indication - n/a -), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a -), [EMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a -), [PARACETAMOL] (C - Product used for unknown indication - n/a -), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a -), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a -)	CSR
EU-EC-1000795936	05/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[BUMETANIDE (BUMETANIDE)] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [PANTOPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [DANESATAN] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [SIBAMFENTIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [INSULIN, INSULIN HUMAN] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [METOLAZONE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [TAMBULOSIN, TAMBULOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000795944	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[ASCORBIC ACID] (C - Product used for unknown indication - n/a - [n/a] - 500mg - n/a), [BISACODYL] (C - Product used for unknown indication - n/a - [n/a] - 10mg - n/a), [CLOMPRAMINE] (C - Product used for unknown indication - n/a - [n/a] - 200mg - n/a), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a] - 20mg - n/a), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [VALPROIC ACID] (C - Product used for unknown indication - n/a - [n/a] - 2000mg - n/a), [VITAMIN D, CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000795923	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Acute respiratory failure (6d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000796022	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[INSULIN DETEMIR (INSULIN DETEMIR)] (C - Diabetes mellitus - n/a - [n/a] - n/a - Unknown), [SEVELAMER (SEVELAMER, SEVELAMER CARBONATE)] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [CYANOCOBALAMIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [MEGLUMINE AMIODOLATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [MODURNE] (C - n/a - n/a - [n/a] - n/a - Unknown), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [SODIUM POLYSTYRENE SULFONATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	CSR
EU-EC-1000795965	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac failure (30m - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Fatigue (8h - Unknown -), Feeling cold (20h - Unknown -), Hypohidrosis (20h - Unknown -), Hypersomnia (8h - Unknown -), Hypertension (30m - Fatal - Results in Death), Hness (n/a - Unknown -), Mobility decreased (n/a - Unknown -), Tremor (8h - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[WARFARIN SODIUM] (C - Cardiac failure congestive, Phlebitis - n/a - [n/a] - n/a - Unknown)	CSR
EU-EC-1000797414	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000797428	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000797367	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000797329	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000797371	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Axillary pain (2d - Not Recovered/Not Resolved -), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR
EU-EC-1000797423	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000797403	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000797478	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Product used for unknown indication - n/a -), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a -), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - Product used for unknown indication - n/a -), [CARVEDILOL] (C - Product used for unknown indication - n/a -), [CYCLOBENZAPRINE] (C - Product used for unknown indication - n/a -), [DOCUATE SODIUM] (C - Product used for unknown indication - n/a -), [FERROUS SULFATE] (C - Product used for unknown indication - n/a -), [GLYCERYL TRINITRATE] (C - Product used for unknown indication - n/a -), [SUAMFENESIN] (C - Product used for unknown indication - n/a -), [HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - n/a -), [INSULIN BOVINE ISOPHANE] (C - Product used for unknown indication - n/a -), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a -), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BIF] (C - n/a - n/a -), [ROBUVASTATIN, ROBUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a -), [SPRONOLACTONE] (C - Product used for unknown indication - n/a -), [FRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Product used for unknown indication - n/a -), [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a -)	CSR
EU-EC-1000795219	04/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000797393	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Aspiration (n/a - Fatal - Results in Death), Asthma (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [AMBIKULIN, AMBIKULIN TRIHYDRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a)	CSR

EU Local Number	EY Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Purpose	Literature Reference	Patient Age Group	Patient Sex (as per reporter)	Patient Sex	Patient Race	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form	
										Death (14 - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Emphysema (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Left atrial dilation (n/a - Fatal - Results in Death), Lung consolidation (n/a - Fatal - Results in Death), Lung opacity (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Oropharyngeal pain (n/a - Fatal - Results in Death), Pulmonary granuloma (n/a - Fatal - Results in Death), Pulmonary hilar mass (n/a - Fatal - Results in Death), Pulmonary mass (n/a - Fatal - Results in Death), Respiratory tract congestion (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	[GLUCOSAMINE, CHONDROITIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [TAMSOLOSIN, TAMSOLOSIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [THAMINE HYDROCHLORIDE, RETNOL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])			
EU-EC-1000778372	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778300	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Athensia (44 - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Decreased appetite (44 - Fatal - Results in Death), Food refusal (44 - Fatal - Results in Death), Memory impairment (44 - Fatal - Results in Death), Mobility decreased (44 - Fatal - Results in Death), Somnolence (44 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778306	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), General physical health deterioration (14 - Fatal - Results in Death), Malaise (44 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	RENILVA [SEVELAMER CARBONATE] (C - Product used for unknown indication - n/a - [n/a - 800mg - n/a]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - 81mg - n/a]), [AMLODIPINE BESILATE, ATORVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), [DOLECALIFEROL] (C - Product used for unknown indication - n/a - [n/a - 1000] - n/a), [CYANOCOBALAMIN, VITAMIN B12] (C - Product used for unknown indication - n/a - [n/a - 1000ug - n/a]), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a - 80mg - n/a]), [METOPROLOL, METOPROLOL TARTRATE Ph. Eur.] (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a])		ICSR
EU-EC-1000778456	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778497	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Mental status changes (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	ANORD [EMECLONUM BROMIDE, VILANTEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), MELTOWN [MELTANOLIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PROGLITAZONE [PROGLITAZONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), SYNVALIA [EMTRICITABINE, TENOFOVIR ALFANEMATE FUMARATE, DARUNAVIR ETHANOLATE, COBICISTAT, EMTRICITABINE, TENOFOVIR ALFANEMIDE, DARUNAVIR, COBICISTAT] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), VICTOZA [LIRAGLUTIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [INSULIN DEGLUCOSE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [RISPERIDONE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])		ICSR
EU-EC-1000778916	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (84 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778540	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778626	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a -), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a -), [DOLECALIFEROL] (C - Product used for unknown indication - n/a -), [DOUCSATE SODIUM] (C - Product used for unknown indication - n/a -), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a -), [MACRODOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACRODOL 3305] (C - Product used for unknown indication - n/a -), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPH] (C - Product used for unknown indication - n/a -), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Product used for unknown indication - n/a -)		ICSR
EU-EC-1000778794	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (34 - Fatal - Results in Death, Other Medically Important Condition), Chills (34 - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Decreased appetite (34 - Fatal - Results in Death), Headache (34 - Fatal - Results in Death), Nausea (34 - Fatal - Results in Death), Psychomotor hyperactivity (34 - Fatal - Results in Death), Pyrexia (28 - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition), Vaccination site pain (34 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778816	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Athensia (n/a - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death), Respiratory tract congestion (n/a - Fatal - Results in Death), Tachycardia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1(DP) - Intramuscular])	MELTOWN [MELTANOLIN] (C - n/a - n/a -), [CLONAZEPAM] (C - n/a - n/a -), [FLUNISULIDE] (C - n/a - n/a -), [MACRODOL 3305] (C - n/a - n/a -), [MAGNESIUM HYDROXIDE] (C - n/a - n/a -), [DIMEPRAZOLE] (C - n/a - n/a -), [PARACETAMOL] (C - n/a - n/a -), [TAMSOLOSIN HYDROCHLORIDE] (C - n/a - n/a -)		ICSR
EU-EC-1000778204	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Hives (14 - Fatal - Results in Death), Syncope (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[ALENDRONATE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Oral]), [ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a - [n/a - 1(DP) - Oral])		ICSR
EU-EC-1000778292	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[ADOP [BRINZOLAMIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Ophthalmic]), BRIVACT [BRIVARACETAM] (C - Product used for unknown indication - n/a - [n/a - n/a - Topical]), [BACITRACIN ZINC, NEDOMYON SULFATE, POLYMYXIN B SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Topical]), [CALCIUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a - 600mg - Oral])		ICSR
EU-EC-1000778297	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778250	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778267	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[DOLECALIFEROL] (C - Product used for unknown indication - Unknown -), [GLATRAMER, GLATRAMER ACETATE] (C - Product used for unknown indication - Unknown -), [HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), [HYDROXYZINE] (C - Product used for unknown indication - Unknown -), [LEVONORGESTREL, LEVONORGESTREL, MIRONORGESTREL] (C - Product used for unknown indication - Unknown -), [PREDNISONE] (C - Product used for unknown indication - Unknown -), [FRANCOLOXOL] (C - Product used for unknown indication - Unknown -), [NALACICLOVIR HYDROCHLORIDE] (C - Product used for unknown indication - Unknown -)		ICSR
EU-EC-1000778347	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778346	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778348	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778306	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778357	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	FENTANYL [FENTANYL, FENTANYL CITRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [HYDROCODONE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-1000778245	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778268	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778815	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Bradycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (74 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death), Diarrhoea haemorrhagic (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypersensitive to stimuli (74 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	HYDROCORTISONE [HYDROCORTISONE, HYDROCORTISONE SODIUM SUCCINATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [CANNABIS] (C - n/a - Unknown - [n/a - n/a - n/a]), [DULOXETINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [FAMOTIDINE] (C - n/a - Unknown - [n/a - n/a - n/a]), LISINAPRIL [LISINAPRIL DIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [MIFYLOXIME] (C - n/a - Unknown - [n/a - n/a - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [DOXYMORPHONE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [SIBRAFATIN] (C - n/a - Unknown - [n/a - n/a - n/a])		ICSR
EU-EC-1000778816	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Fatal - Results in Death), Death (14 - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Posturing (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778840	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778808	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ALLORIPNOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [CARVEDILOL] (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [VALPROIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ZIPRASIDONE] (C - n/a - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-1000778921	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[LYRCA [PREGABALIN] (C - Product used for unknown indication - Unknown - [n/a - 200mg - Unknown]), [ATORVASTATIN CALCIUM] (C - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]), [FLUCLOXACIL HYDROCHLORIDE] (C - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]), [MAGNESIUM OXIDE] (C - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]), [METOPROLOL TARTRATE] (C - Product used for unknown indication - Unknown - [n/a - 25mg - Unknown]), [DIMEPRAZOLE] (C - Product used for unknown indication - Unknown - [n/a - n/a - Unknown]), [POTASSIUM CHLORIDE] (C - Product used for unknown indication - Unknown - [n/a - 20mg - Unknown])		ICSR
EU-EC-1000778035	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Chronic kidney disease (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Pneumonia (14 - Fatal - Results in Death), Septic shock (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778964	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Urinary tract infection (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778719	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778199	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Malaise (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	[ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), [CARVEDILOL] (C - Product used for unknown indication - n/a - [n/a - 25mg - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral]), [LEVOTHYRONE, LEVOTHYRONE SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 2.5mg - Oral]), [PANTOPRAZOLE SODIUM SEQUIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [PHENOBARBITAL, PHENOBARBITAL SODIUM] (C - Product used for unknown indication - n/a - [n/a - 60mg - Oral]), [TERAZOSIN, TERAZOSIN HYDROCHLORIDE, TERAZOSIN HYDROCHLORIDE DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Oral])		ICSR
EU-EC-1000778120	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiogenic shock (14 - Fatal - Results in Death), Cold sweat (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Septic (14 - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	
EU-EC-1000778121	03/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Abdominal pain (74 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Diarrhoea (74 - Fatal - Results in Death), Injection site pain (74 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	Not reported	ICSR	

EU Local Number	EV Category Review Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Purpose	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Chirality	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	CSR Form
EU-EC-1000771251	02/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-1000771491	02/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-1000771521	02/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Malaise (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	OXYBUTYRIN HYDROCHLORIDE (OXYBUTYRIN HYDROCHLORIDE) (C - Hypertonic bladder - Unknown - [n/a - n/a - n/a]), TRUCLITY (DULAGLUTIDE) (C - Type 2 diabetes mellitus - Unknown - [n/a - n/a - n/a]), ESCITALOPRAM, ESCITALOPRAM OXALATE (C - Generalised anxiety disorder - Unknown - [n/a - n/a - n/a]), (EZETIMIBE) (C - Low density lipoprotein increased - Unknown - [n/a - n/a - n/a]), HYDROCHLOROTHIAZIDE (C - Hypertension - Unknown - [n/a - n/a - n/a]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Hypertension - Unknown - [n/a - n/a - n/a]), TAMBULOGIN HYDROCHLORIDE (C - Prostatism/eggl - Unknown - [n/a - n/a - n/a]), (AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE) (C - Product used for unknown indication - n/a - [n/a - 5mg - Unknown]), (METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF) (C - Product used for unknown indication - n/a - [n/a - 1000mg - Unknown]), (OMEPRazole, OMEPRazole SODIUM) (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), (SIMVASTATIN) (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown])	CSR
EU-EC-1000771541	02/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Bedridden (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-1000771618	02/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Arthralgia (n/a - Not Resolved/Not Resolved -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Impaired renal ability (n/a - Fatal - Results in Death, Disability), Malaise (n/a - Fatal - Results in Death), Pain (n/a - Not Resolved/Not Resolved -), Vaccination site pain (n/a - Not Resolved/Not Resolved -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-1000772013	02/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Unresponsive to stimuli (1d - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-1000773492	01/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Blood pressure increased (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Death (1d - Fatal - Results in Death), Heart rate increased (n/a - Fatal - Results in Death), Respiratory arrest (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	LEVITRACETAM (LEVITRACETAM) (C - n/a - n/a - [n/a - n/a - n/a]), (BRONCHODINE, BRONCHODINE TARTRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (COLICALCIFEROL) (C - n/a - n/a - [n/a - n/a - n/a]), (SUCSALATE SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]), (DONEPEZIL HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (METOPROLOL, METOPROLOL TARTRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]), (SIBNOSIDE B) (C - n/a - n/a - [n/a - n/a - n/a]), (VALPROIC ACID) (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000773621	01/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (BISACODYL) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (SALICILIC ACID) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (SUCSALATE SODIUM CASIN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (SUCSALATE SODIUM CASIN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (HYDROXYMINE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (LEVOMENTHOL, CAUFRUT OIL, EUCALYPTUS OIL, METHYL SALICYLATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (LORAZEPAM) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (MAGNESIUM HYDROXIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (MORPHINE, MORPHINE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (PREDNISONE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (SALBUTAMOL SULFATE, (P)RATROPOL BROMIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (TAMBULOGIN, TAMBULOGIN HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (VASELIN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000773915	01/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Condition aggravated (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (1d - Fatal - Results in Death), Unresponsive to stimuli (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-1000773978	01/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown)	Not reported	CSR
EU-EC-10007743746	28/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - intramuscular])	Not reported	CSR
EU-EC-10007744248	28/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Anaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac failure congestive (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Condition aggravated (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Pyrexia (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ACETYLSALICYLIC ACID (C - n/a - n/a - [n/a - 81mg - n/a]), (AMODARONE, AMODARONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 1000mg - n/a]), (CASSIA) (C - n/a - n/a - [n/a - 5mg - n/a]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - n/a - n/a - [n/a - 40mg - n/a]), (LISINAPRIL, LISINAPRIL DIHYDRATE) (C - n/a - Unknown - [n/a - 10mg - n/a]), (MEMENTAN HYDROCHLORIDE) (C - n/a - n/a - [n/a - 28mg - n/a]), (METOPROLOL, METOPROLOL TARTRATE) (C - n/a - n/a - [n/a - 25mg - n/a]), (OMEPRazole, PANTOPRAZOLE, PANTOPRAZOLE SODIUM) (C - n/a - n/a - [n/a - 40mg - n/a]), (POTASSIUM CHLORIDE) (C - n/a - n/a - [n/a - 10meq - n/a]), (SIMVASTATIN) (C - n/a - n/a - [n/a - 40mg - n/a])	CSR
EU-EC-10007741942	27/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007741948	27/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007741054	27/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Pain (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007741088	27/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (2d - Fatal - Results in Death), Pneumonia aspiration (n/a - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	OLANZAPINE (OLANZAPINE) (C - n/a - n/a -), (CARVEDILOL) (C - n/a - n/a -), (DILTIAZEM HYDROCHLORIDE) (C - n/a - n/a -), (PHENYTOIN SODIUM) (C - n/a - n/a -), (AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (ATORVASTATIN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (SABAPENTIN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (SLUDGE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (LINALGIFIN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (LISINAPRIL, LISINAPRIL DIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (NAPROXEN, NAPROXEN SODIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (TRIMOL, TIMOLOL MALEATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Ophthalmic]), (TRAZODONE, TRAZODONE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (ASCORBIC ACID, RIBOFLAVIN, DEXTRIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (LOSARTAN, LOSARTAN POTASSIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-10007736338	26/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Dyspnoea (2d - Fatal - Results in Death), Hypoxoemia (2d - Fatal - Results in Death), Palpitations (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007716198	25/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Dizziness (n/a - Fatal - Results in Death), Fat (n/a - Fatal - Results in Death), Feeling abnormal (n/a - Fatal - Results in Death), Memory impairment (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007725693	25/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007729056	25/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	Not reported	CSR
EU-EC-10007728557	25/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cardiac arrest (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Crepitations (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Productive cough (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 2DF] - intramuscular)	Not reported	CSR
EU-EC-10007727273	25/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	HEALTHY EYES (ASCORBIC ACID, BETA-CAROTENE, COPPER, DUNAUELLA SALINA, SELENIUM, XANTHOPYL, ZEAXANTHIN, ZINC CHELATE) (C - n/a - n/a -), (ATORVASTATIN) (C - n/a - n/a -), (DIPHENHYDRAMINE) (C - n/a - n/a -), (FUROSEMIDE) (C - n/a - n/a -), (SABAPENTIN) (C - n/a - n/a -), (GLYCERYL TRINERATE) (C - n/a - n/a - [n/a - n/a - n/a]), (SODIUM MONONITRATE) (C - n/a - n/a -), (LOPERAMIDE HYDROCHLORIDE, LOPERAMIDE OXIDE) (C - n/a - n/a -), (METOPROLOL, SUCCINATE) (C - n/a - n/a -), (POTASSIUM CLAVULANATE) (C - n/a - n/a -), (VALPROIC ACID) (C - n/a - n/a -)	CSR
EU-EC-10007727291	25/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	OLANZAPINE (OLANZAPINE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (SOLFENACIN, SOLFENACIN SUCCINATE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (TRAMADOL, TRAMADOL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (ACETYLSALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a]), (ALLOPURINOL) (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), (AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE) (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), (FUROSEMIDE) (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), (GIBENCLAMOL) (C - Product used for unknown indication - n/a - [n/a - 2.5mg - n/a]), (LOSARTAN, LOSARTAN POTASSIUM) (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), (METOPROLOL, METOPROLOL TARTRATE) (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), (POTASSIUM CHLORIDE) (C - Product used for unknown indication - n/a - [n/a - 10meq - n/a]), (PRAVASTATIN, PRAVASTATIN SODIUM) (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a])	CSR
EU-EC-10007727370	25/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Dyspnoea (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007727378	25/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Unresponsive to stimuli (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007740461	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007705196	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (22d - Fatal - Results in Death), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)	Not reported	CSR
EU-EC-10007705188	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 pneumonia (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007709881	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Unknown)	Not reported	CSR
EU-EC-10007719468	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007709818	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007711418	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Bradycardia (n/a - Fatal - Results in Death), Chills (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Pains (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007723268	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR
EU-EC-10007712900	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - intramuscular)	Not reported	CSR

EU Local Number	EV Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Subsequent Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
EU-EC-1000771304	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (16 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	EVISTA [RALOXIFENE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MELATONIN [MELATONIN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), XARELTO [RIVAROXABAN] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ASCORBIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), DOLECALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), CRANBERRY (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), DOUCASATE SODIUM CASANTHRANOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FAMOTIDINE, FAMOTIDINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FOLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FUROSEMIDE, FUROSEMIDE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LACTOBACILLUS ACIDOPHILUS (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LEVOTHYROXINE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MAGNESIUM OXIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MINERALS NOS, VITAMINS NOS (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MIRTAZAPINE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SALBUTAMOL SULFATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SERTRALINE, SERTRALINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SIMETICONE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), VALPROATE SEMISODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ZINC (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000771307	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardio-respiratory distress (6 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (54 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (54 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical condition abnormal (54 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (54 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	BEVILAMER CARBONATE [BEVILAMER CARBONATE] (C - Product used for unknown indication - n/a - [n/a - 80mg - Unknown]), ASCORBIC ACID (C - Product used for unknown indication - n/a - [n/a - 500mg - Unknown]), CARVEDILOL (C - Product used for unknown indication - n/a - [n/a - 3.125mg - Unknown]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), THIAMINE (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), VITAMINS NOS (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000771318	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Headache (14 - Fatal - Results in Death), Injection site pain (14 - Fatal - Results in Death), Vomiting (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), SABAPENTIN (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LEVOTHYROXINE, LEVOTHYROXINE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), PRAVASTATIN, PRAVASTATIN SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-1000771303	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	No	No	Death (n/a - Fatal - Results in Death)	SPIEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - n/a - Intramuscular)	Not reported	CSR
EU-EC-1000771308	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cough (34 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Dyspnoea (34 - Fatal - Results in Death), Hyperaesthesia (34 - Fatal - Results in Death), Mental status changes (34 - Fatal - Results in Death), Oxygen saturation decreased (34 - Fatal - Results in Death), Pyrexia (34 - Fatal - Results in Death), Screening (n/a - Fatal - Results in Death), Speech disorder (34 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - n/a - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000771374	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - n/a - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000771348	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Dysarthria (24 - Fatal - Results in Death), Fatigue (34 - Fatal - Results in Death), Malaise (34 - Fatal - Results in Death), Memory impairment (34 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - n/a - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000771397	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000771434	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Asthma (14 - Fatal - Results in Death), COVID-19 (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - Intramuscular)	ENSURE CLEAR [CARBOHYDRATES NOS, MINERALS NOS, PROTEINS NOS, VITAMINS NOS] (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), ASCORBIC ACID (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), DOUCASATE SODIUM SEMIHOSEDES (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), FAMOTIDINE, FAMOTIDINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), HYDROMELLOSE, GLYCEROL, MACROGOL 400, POLYVINYL ALCOHOL, PROPYLENE GLYCOL, VASELINE LIQUID PARAFFIN (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), MACROGOL 3350 (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), METOPROLOL TARTRATE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), POTASSIUM CHLORIDE, GLUCOSE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), TRAMADOL, TRAMADOL HYDROCHLORIDE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a])	CSR
EU-EC-1000771432	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	FUROSEMIDE, FUROSEMIDE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), METOPROLOL, METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TRAMADOL, TRAMADOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), VITAMINS NOS (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a])	CSR
EU-EC-1000771467	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Dizziness (14 - Fatal - Results in Death), Malaise (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000771495	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000771543	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - n/a)	KETOCOANAZOLE [KETOCOANAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), ATORVASTATIN (C - n/a - n/a - [n/a - n/a - n/a]), BUPROFEN (C - n/a - n/a - [n/a - n/a - n/a]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - n/a - n/a - [n/a - n/a - n/a]), SERTRALINE, SERTRALINE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000771541	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Syncope (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	DOXYBUTYRIN HYDROCHLORIDE [DOXYBUTYRIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 15mg - n/a]), CAPTOPRIL (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), SABAPENTIN (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a]), HYDRALAZINE (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a]), INDOMETHACIN SODIUM TRIHYDRATE (C - Product used for unknown indication - n/a - [n/a - 75mg - n/a]), METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), POTASSIUM CHLORIDE (C - Product used for unknown indication - n/a - [n/a - 20meq - n/a]), SPONDYLACTINE (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]), TRAMADOL, TRAMADOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 4mg - n/a]), VITAMINS NOS, VITAMINS NOS (C - Product used for unknown indication - Unknown - [n/a - 75mg - n/a]), VITAMINS NOS, VITAMINS NOS (C - Product used for unknown indication - Unknown - [n/a - 240mg - n/a])	CSR
EU-EC-1000771592	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-1000771596	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cardiac failure congestive (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - Intramuscular)	ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PAROXETINE, PAROXETINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-1000771595	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - Intramuscular)	PIROXICAM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - Not applicable - [n/a - 81mg - n/a]), ALLUCURINOL (C - Product used for unknown indication - Not applicable - [n/a - 300mg - n/a]), BACLOFEN (C - Product used for unknown indication - Not applicable - [n/a - 10mg - n/a]), ELORBETASOL PROPIONATE (C - Product used for unknown indication - Not applicable - [n/a - n/a - n/a]), CYANOCOBALAMIN (C - Product used for unknown indication - Not applicable - [n/a - n/a - n/a]), FISH OIL (C - Product used for unknown indication - Not applicable - [n/a - n/a - n/a]), NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE (C - Product used for unknown indication - Not applicable - [n/a - 10mg - n/a]), SALBUTAMOL SULFATE (C - Product used for unknown indication - Not applicable - [n/a - n/a - n/a]), PROLA [DENOSUMAB] (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), ALPHATOCOPHEROL ACETATE, LUTEN (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), ATORVASTATIN (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), FLUCICAZONE PROPIONATE, SALMETEROL (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), FUROSEMIDE, POTASSIUM CHLORIDE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), SABAPENTIN (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), HYDROCHLOROTHIAZIDE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), HYDROCODONE BITARTRATE, PARACETAMOL (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), LANOPRazole (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), LEVOSALBUTAMOL (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), LOSARTAN, LOSARTAN POTASSIUM (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), MELOXICAM (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), NYSTATIN (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), PARACETAMOL, CAFFEINE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), PIVOIONE, POLYVINYL ALCOHOL (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), SALBUTAMOL SULFATE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), TITROPIUM, TITROPIUM BROMIDE, TITROPIUM BROMIDE MONOHYDRATE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a])	CSR
EU-EC-1000768050	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - n/a - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-1000768153	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10007700182	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10007705537	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-1000770562	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10007701450	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthma (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fat (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10007701484	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-10007701512	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Unknown)	Not reported	CSR
EU-EC-10007701517	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	AMLODIPINE, AMLODIPINE BESILATE (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), SABAPENTIN (C - Neutrogen - n/a - [n/a - 100mg - Oral]), LOSARTAN POTASSIUM (C - HyperTension - n/a - [n/a - 50mg - Oral]), DULOXETINE [DULOXETINE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), BUPROFEN [BUPROFEN, BUPROFEN SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), CRANBERRY (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), QUINAPRIL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LACTOBACILLUS ACIDOPHILUS (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MACROGOL 3350 (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TRAMADOL, TRAMADOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), VITAMIN D (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ZINC (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	CSR
EU-EC-10007701757	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Bain hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	KEPPRA [LEVETIRACETAM] (C - Seizure - n/a - [n/a - n/a - Unknown]), LAMOTRIGINE (C - Seizure - n/a - [n/a - n/a - Unknown]), PHENOBARBITAL, PHENOBARBITAL SODIUM (C - Seizure - n/a - [n/a - n/a - Unknown])	CSR
EU-EC-10007701765	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10007689975	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10007680151	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1DP] - Intramuscular)	Not reported	CSR
EU-EC-10007680152	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (136 - Fatal - Results in Death), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1DP] - Intramuscular)	TRILICITY [DULAGLUTIDE] (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), ATORVASTATIN (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), FUROSEMIDE (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), SABAPENTIN (C - Product used for unknown indication - Unknown - [n/a - n/a - n/a])	CSR

EU Local Number	EV Entry Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Race	Parent Child Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
												[GLPZOLE] (C - Product used for unknown indication - Unknown -), [LORATADINE] (C - Product used for unknown indication - Unknown -), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - Unknown -), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BIF] (C - Product used for unknown indication - Unknown -), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - Unknown -), [EMEPRAZOLE] (C - Product used for unknown indication - Unknown -)	
EU-EC-1000780363	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-1000781506	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthenia (n/a - Fatal - Results in Death), Stomatitis (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Gastrointestinal haemorrhage (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a] - 1[Df] - Intramuscular)	[AMLODIPINE, AMLODIPINE BESILATE] (C - Product used for unknown indication - n/a - [n/a] - 10mg - Oral), [BENZEPHRI] (C - Product used for unknown indication - n/a - [n/a] - 20mg - Oral), [DABEPENTIN] (C - Product used for unknown indication - n/a - [n/a] - 400mg - Oral), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a] - 100mg - Oral), [ROSLIVASTATIN, ROSUVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a] - 10mg - Oral)	ICSR
EU-EC-1000781119	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-1000781230	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-1000781417	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Internal haemorrhage (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-1000780515	19/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Abdominal pain (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Injection site pain (n/a - Unknown -), Vomiting (n/a - Unknown -)	SPRIVEX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-1000780369	19/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Injection site pain (n/a - Unknown -), Vomiting (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-1000783855	19/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Immature (4d - Fatal - Results in Death, Other Medically Important Condition), Pruritus (8d - Fatal - Results in Death), Respiratory disorder (3d - Fatal - Results in Death), Unresponsive to stimuli (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Product used for unknown indication - n/a -), [ELIQUIS (APIXABAN)] (C - Product used for unknown indication - n/a -), [MELATONIN (MELATONIN)] (C - Product used for unknown indication - n/a -), [METHOTREXATE (METHOTREXATE)] (C - Product used for unknown indication - n/a -), [PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE)] (C - Product used for unknown indication - n/a -), [ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a -), [ATORVASTATIN] (C - Product used for unknown indication - n/a -), [CALCIUM] (C - Product used for unknown indication - n/a -), [DIOXIN] (C - Product used for unknown indication - n/a -), [FOLIC ACID] (C - Product used for unknown indication - n/a -), [LATANOPROST] (C - Product used for unknown indication - n/a -), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a -), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a), [PRENOSIN] (C - Product used for unknown indication - n/a -)	ICSR
EU-EC-1000780569	18/02/2021	Spontaneous	Not Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Body temperature abnormal (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Dyspnoea (3d - Fatal - Results in Death), Fatigue (1d - Fatal - Results in Death), Feeling abnormal (3d - Fatal - Results in Death), Limb discomfort (3d - Fatal - Results in Death), Swelling (2d - Fatal - Results in Death), Unresponsive to stimuli (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[REVELIA (SEVELAMER CARBONATE)] (C - Product used for unknown indication - n/a - [n/a] - 800mg - Unknown), [ACETYLSALICYLIC ACID] (C - Product used for unknown indication - n/a - [n/a] - 81mg - Unknown), [CALCIUM ACETATE] (C - Product used for unknown indication - n/a - [n/a] - Unknown), [ENKALCET] (C - Product used for unknown indication - n/a - [n/a] - 80mg - Unknown), [FUROSEMIDE] (C - Product used for unknown indication - n/a - [n/a] - Unknown), [GLPZOLE] (C - Product used for unknown indication - n/a - [n/a] - 5mg - Unknown), [LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a] - Unknown), [EMEPRAZOLE] (C - Product used for unknown indication - n/a - [n/a] - 20mg - Unknown), [RIFAMPICIN] (C - Product used for unknown indication - n/a - [n/a] - Unknown), [VITAMIN D] (C - Product used for unknown indication - n/a - [n/a] - Unknown)	ICSR
EU-EC-10007805976	18/02/2021	Spontaneous	Not Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007802441	17/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Hypoglycaemia (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death), Tachypnoea (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[ASCORBIC ACID] (C - Product used for unknown indication - n/a - [n/a] - n/a), [DOUSATE SODIUM, CASIA] (C - Product used for unknown indication - n/a - [n/a] - n/a), [VACCINIUM MACROCARPON (CRANBERRY FRUIT EXTRACT)] (C - Product used for unknown indication - n/a - [n/a] - n/a)	ICSR
EU-EC-10007843111	17/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[JANUVIA (SITAGLIPTIN, SITAGLIPTIN PHOSPHATE, SITAGLIPTIN PHOSPHATE MONOHYDRATE)] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [LANTUS (INSULIN GLARGINE)] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [ALENDRONATE SODIUM, ALENDRONATE SODIUM TRIHYDRATE, ALENDRONIC ACID] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [DOUSATE SODIUM] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [LEVOTHYROXINE SODIUM] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [BIMASTATIN] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [TRACOLONE (TRACOLONE HYDROCHLORIDE)] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [CARBIDOPA, LEVODOPA (CARBIDOPA, LEVODOPA)] (C - Product used for unknown indication - n/a - [n/a] - n/a - Oral), [MELATONIN (MELATONIN)] (C - Product used for unknown indication - n/a - [n/a] - 3mg - Oral), [RIVASTIGMINE (RIVASTIGMINE, RIVASTIGMINE HYDROGEN TARTRATE)] (C - Product used for unknown indication - n/a - [n/a] - n/a - n/a), [AMLODIPINE BESILATE] (C - Product used for unknown indication - n/a - [n/a] - 5mg - Oral), [ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a - [n/a] - 1000mg - Oral), [ATORVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a] - 20mg - Oral), [CASIA] (C - Product used for unknown indication - n/a - [n/a] - 17.2mg - Oral), [METFORMIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - 1000mg - Oral), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Oral)	ICSR
EU-EC-1000784194	17/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Respiratory arrest (1d - Fatal - Results in Death), Vomiting (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - n/a - [n/a] - 1000mg - Oral), [ATORVASTATIN CALCIUM] (C - Product used for unknown indication - n/a - [n/a] - 20mg - Oral), [CASIA] (C - Product used for unknown indication - n/a - [n/a] - 17.2mg - Oral), [METFORMIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - 1000mg - Oral), [VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a] - 1[Df] - Oral)	ICSR
EU-EC-1000784423	17/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthma (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a] - n/a - Intramuscular)	[REVELIA (SEVELAMER CARBONATE)] (C - n/a - n/a - [n/a] - n/a - Oral), [FLUTICASON PROPRIONATE] (C - n/a - n/a - [n/a] - n/a - Oral), [MACRODOL 3350] (C - n/a - n/a - [n/a] - n/a - Oral), [EMEPRAZOLE] (C - n/a - n/a - [n/a] - 20mg - Oral), [PARACETAMOL] (C - n/a - n/a - [n/a] - n/a - Oral), [ISOTALOL, SOTALOL HYDROCHLORIDE] (C - n/a - n/a - [n/a] - 80mg - Oral)	ICSR
EU-EC-1000784467	17/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Decreased appetite (2d - Fatal - Results in Death), Depressed level of consciousness (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [DONEPEZIL HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [MEMANTINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [MIRTAZAPINE] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - Product used for unknown indication - n/a - [n/a] - n/a - Unknown)	ICSR
EU-EC-10007847975	17/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007829221	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Headache (n/a - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007831278	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007831388	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007831424	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (2d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007831557	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Syncope (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007831664	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007831665	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (6d - Fatal - Results in Death), General physical health deterioration (6d - Fatal - Results in Death), Hypoglycaemia (6d - Fatal - Results in Death), Hypertensive to stimuli (6d - Fatal - Results in Death), Somnolence (6d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)	[HYDROCHLOROTHIAZIDE] (C - Product used for unknown indication - n/a - [n/a] - 12.5mg - n/a), [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a] - 25mg - n/a), [TERAZOSIN, TERAZOSIN HYDROCHLORIDE DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a] - 5mg - Oral), [VALPROATE SEMISODIUM] (C - Product used for unknown indication - n/a - [n/a] - 750mg - n/a)	ICSR
EU-EC-10007831775	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (23d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007831944	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007832065	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007832101	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR
EU-EC-10007832323	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Body temperature increased (1d - Fatal - Results in Death), Complication associated with device (1d - Fatal - Results in Death), Cough (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Dyspnoea (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a] - 1[Df] - Intramuscular)		ICSR

EU Local Number	EV Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Purpose	Literature Reference	Patent Age Group	Patent Age Group (as per reporter)	Patent Sex	Patent Chm Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Extracting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
										Hypoxia (14 - Fatal - Results in Death), Secretion discharge (14 - Fatal - Results in Death)			
EU-EC-1000762448	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	BUPROPION HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ZOLPIDEM TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000762073	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Cough (24 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Dyspnoea (24 - Fatal - Results in Death), Feeling abnormal (24 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1(DP) - Intramuscular])	DELTAZEM, DELTAZEM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), ERYTHROMYCIN (C - Product used for unknown indication - n/a - [n/a - 4% - Unknown]), FERROUS ION (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), FOLIC ACID (C - Product used for unknown indication - n/a - [n/a - 1mg - Unknown]), FUROSEMIDE, FUROSEMIDE SODIUM (C - Product used for unknown indication - n/a - [n/a - 40mg - Unknown]), HYDROXYCHLOROQUINE SULFATE (C - Product used for unknown indication - n/a - [n/a - 250F - Unknown]), KETOTIFEN (C - Product used for unknown indication - n/a - [n/a - 20mg - Unknown]), METOPROLOL SUCONATE (C - Product used for unknown indication - n/a - [n/a - 200mg - Unknown])	ICSR
EU-EC-1000762079	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	CETIRIZINE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), PARACETAMOL (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000762073	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (54 - Fatal - Results in Death), Oedema (54 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	CARBIDOPA, LEVODOPA [CARBIDOPA, LEVODOPA] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), OXYBUTYRIN [OXYBUTYRIN, OXYBUTYRIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FINASTERIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FUROSEMIDE, FUROSEMIDE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SUAR (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LACTOBIACILLUS (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), METOPROLOL SUCONATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MINERALS NOS, VITAMINS NOS (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PRAVASTATIN, PRAVASTATIN BORATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TIMOLOL, TIMOLOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TIMOLOL MALEATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), VITAMINS NOS (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000762425	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Asthma (54 - Fatal - Results in Death), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-1000762481	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-1000762481	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Aneurysm ruptured (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebral haemorrhage (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of consciousness (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (24 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-1000762059	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Body temperature increased (24 - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Headache (24 - Fatal - Results in Death), Lethargy (24 - Fatal - Results in Death), Neck pain (24 - Fatal - Results in Death), Respiration abnormal (S/n/a - Fatal - Results in Death), Tremor (24 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LEVETIRACETAM [LEVETIRACETAM] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PROBENECID NOS [PROBENECID NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ACEYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), NICLOXVIL SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ATENOLOL, ATENOLOL BPF (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), CEFDIOXIME (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), CHLORTALIDONE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FLUCONAZOLE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), IBUPROFEN, NAPROXEN, NAPROXEN SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MINERALS NOS, VITAMINS NOS (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TOPRAMATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000762067	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-1000762069	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-1000762079	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Fatigue (34 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-1000762046	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-1000762030	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), General physical health deterioration (44 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1(DP) - Intramuscular])	AMYLASE, LIPASE, PROTEASE, PANCREALIPASE, PANCREAS POWDER, PANCREAS POWDER FROM PORCINE, PANCREATIN, PANCREATIN BPF (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ATENOLOL, ATENOLOL BPF (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), BISACODYL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), CALCIUM CITRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), DONEPEZIL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ESOCALOPRAM, ESOCALOPRAM OXALATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ESTRADIOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FAMOTIDINE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FERROUS SULFATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), IBANDRONIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LACTOBIACILLUS ACIDOPHILUS, BIFIDOBACTERIUM BPF (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), MEMANTINE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), POTASSIUM CHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), QUETIAPINE, QUETIAPINE FUMARATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), BIMASTATIN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SODIUM HYDROGEN CARBONATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TOLAMFATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), BIMASTATIN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000762041	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Basal ganglia stroke (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Haemorrhagic stroke (14 - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-1000762040	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Pulse absent (14 - Fatal - Results in Death), Vomiting (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	CYMBALTA [DULOXETINE, DULOXETINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 30mg - Unknown]), ACEYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - 61mg - Unknown]), AMLODIPINE, AMLODIPINE BESILATE (C - Product used for unknown indication - n/a - [n/a - 10mg - Unknown]), ASCORBIC ACID (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown]), CARVEDILOL (C - Product used for unknown indication - n/a - [n/a - 12.5mg - Unknown]), CHLORMADONNE ACETATE (C - Product used for unknown indication - n/a - [n/a - 90ml - Unknown]), FOLIC ACID (C - Product used for unknown indication - n/a - [n/a - 1.5mg - Unknown]), LORAZEPAM (C - Product used for unknown indication - n/a - [n/a - 1.5mg - Unknown]), THIAMINE HYDROCHLORIDE, RETINOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), THIAMINE (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown])	ICSR
EU-EC-1000762056	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	MEMANTINE HYDROCHLORIDE [MEMANTINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), MULTIPLE VITAMINS WITH MINERALS [AMINOACIDIC ACID, BETAINE HYDROCHLORIDE, CHOLINE BITARTRATE, CITRUS LIMON, ECHINACEA PURPUREA ROOT, GLUTAMIC ACID, HYDROXYCHLOROQUINE, HYDROXYMETHYL METHYLAMINE DIGLYCATE POWDER, MALIC ACID, MENTHOL, MENTHOL DIACETATE, METFORMIN, MINERALS NOS, PIPERIN, QUERCETIN DIHYDRATE, ROSA CANINA, RUTOSIDE, VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a - 15ml - n/a]), ASCORBIC ACID (C - Product used for unknown indication - n/a - [n/a - 500mg - n/a]), FAMOTIDINE (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), HYDROXYNAPHTHALENE OLYCOSIDES, SENEGALENSES (C - Product used for unknown indication - n/a - [n/a - 8.5mg - n/a]), MACROGOL 3350 (C - Product used for unknown indication - n/a - [n/a - 7g - n/a])	ICSR
EU-EC-1000762093	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	ANORO [AMELINDIUM BROMIDE, VALANTEROL] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), BUMETANIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), CARVEDILOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FLUTICASON PROPRIONATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), OMEPRAZOLE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), SALBUTAMOL, SALBUTAMOL SULFATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ENDURE PLUS [CARBOHYDRATES NOS, ELECTROLYTES NOS, FATTY ACIDS NOS, MINERALS NOS, PROTEINS NOS, VITAMINS NOS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), RENISLA [SILICUM CARBONATE] (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a]), ACEYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - 81mg - n/a]), CALCIUM ACETATE (C - Product used for unknown indication - n/a - [n/a - 667mg - n/a]), CINACALCET (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), COLECALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), [EUCERIN, UREA, WOOL ALCOHOLS] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - 80mg - n/a]), DLPDZEE (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), OMEPRAZOLE (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), RIFAMPICIN (C - Product used for unknown indication - n/a - [n/a - 300mg - n/a]), PROLIS [BENZOAMINE] (C - n/a - n/a - [n/a - n/a - n/a]), ACEYLSALICYLIC ACID (C - n/a - n/a - [n/a - n/a - n/a]), BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE (C - n/a - n/a - [n/a - n/a - n/a]), CANDESARTAN CILEXTEL (C - n/a - n/a - [n/a - n/a - n/a]), DOLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE (C - n/a - n/a - [n/a - n/a - n/a]), BIMASTATIN (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000762017	12/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Black pain (34 - Fatal - Results in Death), Cardiac disorder (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Dizziness (24 - Fatal - Results in Death), Pain in extremity (34 - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-1000762018	12/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-1000762037	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Cardiac arrest (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ACEYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ATORVASTATIN (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), DONEPEZIL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LISINAPRIL, LISINAPRIL DIHYDRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), LORATADINE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), METOPROLOL TARTRATE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), PENTOPHYLLINE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), TIMOLOL HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000762040	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	FRAXIDONE, FRAXIDONE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), INSULIN LISPRO [INSULIN LISPRO] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), OXYBUTYRIN HYDROCHLORIDE [OXYBUTYRIN HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ACEYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), ALLOPURINOL (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), AMITRIPTYLINE, AMITRIPTYLINE HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE (C - Product used for unknown indication - n/a - [n/a - 80mg - n/a]), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), BACLOFEN (C - Product used for unknown indication - n/a - [n/a - 5mg - n/a]), CANDESARTAN (C - Product used for unknown indication - n/a - [n/a - 32mg - n/a]), COLECALCIFEROL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), FUROSEMIDE, FUROSEMIDE SODIUM (C - Product used for unknown indication - n/a - [n/a - 80mg - n/a]), GABAPENTIN (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), HYDRALAZINE (C - Product used for unknown indication - n/a - [n/a - 50mg - n/a]), PARACETAMOL (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), POTASSIUM CHLORIDE (C - Product used for unknown indication - n/a - [n/a - 20meq - n/a]), TURBEMERG (C - Product used for unknown indication - n/a - [n/a - 400mg - n/a]), CARBELLULOSE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DELTAZEM, DELTAZEM HYDROCHLORIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), DOCSUATE SODIUM (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [ESOCALOPRAM OXALATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), MACROGOL (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), MAGNESIUM HYDROXIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-1000762022	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Cerebrovascular accident (44 - Fatal - Results in Death, Other Medically Important Condition), Death (14 - Fatal - Results in Death), Decreased appetite (44 - Fatal - Results in Death), Grip strength decreased (44 - Fatal - Results in Death), Hemiplegia (44 - Fatal - Results in Death, Other Medically Important Condition), Hypoxia (44 - Fatal - Results in Death), Speech disorder (44 - Fatal - Results in Death), Weight decreased (44 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-1000762030	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Unknown - [n/a - 1(DP) - Intramuscular])		ICSR

EU Local Number	EY Review Date	Report Type	Primary Source Qualification	Primary Source Country	Literature Reference	Patient Age Group	Patient Sex	Patient Race	Patient Weight	Reaction List (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	CSR Form
EU-EC-1000758164	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	ACEFYSALICYLIC ACID] (C - Product used for unknown indication - na - [na] - na - na), ATORVASTATIN] (C - Product used for unknown indication - na - [na] - na - na), DIXOCODONE, DIXOCODONE HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - na), LORAZEPAM] (C - Product used for unknown indication - na - [na] - na - na)	CSR
EU-EC-1000758163	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - na)	BUKETANIDE [BUKETANIDE] (C - Product used for unknown indication - na - [na] - na - na), ELIGUS [APIXABAN] (C - Product used for unknown indication - na - [na] - na - na), DIXOCODONE, DIXOCODONE HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - na), ALEXORONATE SODIUM, ALEXORONATE SODIUM TRIFLUORIDE, ALEXORONIC ACID] (C - Product used for unknown indication - na - [na] - na - na), LUSKOPRIL, LUSKOPRIL DIHYDRATE] (C - Product used for unknown indication - na - [na] - na - na), MELOXICAM] (C - Product used for unknown indication - na - [na] - na - na), MONTELUKAST, MONTELUKAST SODIUM] (C - Product used for unknown indication - na - [na] - na - na), POTASSIUM CHLORIDE] (C - Product used for unknown indication - na - [na] - na - na), PREDNISON] (C - Product used for unknown indication - na - [na] - na - na), PROMETHAZINE, PROMETHAZINE HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - na), TRIAMCINOLONE, TRIAMCINOLONE ACETONIDE] (C - Product used for unknown indication - na - [na] - na - na), DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (C - Product used for unknown indication - na - [na] - na - na), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - Unknown - [na] - 5mg - Unknown), BISOPROLOL, BISOPROLOL FLUMARATE, BISOPROLOL, HEMIFLUMARATE] (C - Product used for unknown indication - Unknown - [na] - 10mg - Unknown), FURSEMIDE] (C - Product used for unknown indication - Unknown - [na] - 50mg - Unknown), BISBORONIC DINATRATE] (C - Product used for unknown indication - Unknown - [na] - 30mg - Unknown), LEVOTHYRONINE, LEVOTHYRONINE SODIUM] (C - Product used for unknown indication - Unknown - [na] - 275mg - Unknown), PARACETAMOL] (C - Product used for unknown indication - Unknown - [na] - 3000mg - Oral), SALINE, SODIUM CHLORIDE] (C - Product used for unknown indication - Unknown - [na] - na - Unknown), CLOPIDOGREL, HYDROGEN SULFATE [CLOPIDOGREL, HYDROGEN SULFATE] (C - Product used for unknown indication - na - [na] - na - Unknown), ASCORBIC ACID, ZINC, COPPER, RETINOL, ALPHA-TOCOPHEROL] (C - Product used for unknown indication - na - [na] - na - Unknown), DOLICALCIFEROL] (C - Product used for unknown indication - na - [na] - na - Unknown), FERROUS GLUCONATE] (C - Product used for unknown indication - na - [na] - na - Unknown), FLUTICASON PROPRIONATE] (C - Product used for unknown indication - na - [na] - na - Unknown), GLYCERYL TRINOTRATE] (C - Product used for unknown indication - na - [na] - na - Sublingual), LUSKOPRIL, LUSKOPRIL DIHYDRATE] (C - Product used for unknown indication - na - [na] - na - Unknown), MACRODOL 3300] (C - Product used for unknown indication - na - [na] - na - Unknown), MAGNESIUM HYDROXIDE] (C - Product used for unknown indication - na - [na] - na - Unknown), METHYL, CAMPHOR, METHYL SALICYLATE] (C - Product used for unknown indication - na - [na] - na - Unknown), METOPROLOL, SULCONATE] (C - Product used for unknown indication - na - [na] - na - Unknown), DINDANETRON] (C - Product used for unknown indication - na - [na] - na - Unknown), SPRONOLACTONE] (C - Product used for unknown indication - na - [na] - na - Unknown), TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - Unknown)	CSR
EU-EC-1000758162	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (14 - Fatal - Results in Death), Feeding disorder (14 - Fatal - Results in Death), Laryngitis (14 - Fatal - Results in Death), Mildly decreased (14 - Fatal - Results in Death), Speech disorder (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (C - Product used for unknown indication - na - [na] - na - na), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - Unknown - [na] - 5mg - Unknown), BISOPROLOL, BISOPROLOL FLUMARATE, BISOPROLOL, HEMIFLUMARATE] (C - Product used for unknown indication - Unknown - [na] - 10mg - Unknown), FURSEMIDE] (C - Product used for unknown indication - Unknown - [na] - 50mg - Unknown), BISBORONIC DINATRATE] (C - Product used for unknown indication - Unknown - [na] - 30mg - Unknown), LEVOTHYRONINE, LEVOTHYRONINE SODIUM] (C - Product used for unknown indication - Unknown - [na] - 275mg - Unknown), PARACETAMOL] (C - Product used for unknown indication - Unknown - [na] - 3000mg - Oral), SALINE, SODIUM CHLORIDE] (C - Product used for unknown indication - Unknown - [na] - na - Unknown), CLOPIDOGREL, HYDROGEN SULFATE [CLOPIDOGREL, HYDROGEN SULFATE] (C - Product used for unknown indication - na - [na] - na - Unknown), ASCORBIC ACID, ZINC, COPPER, RETINOL, ALPHA-TOCOPHEROL] (C - Product used for unknown indication - na - [na] - na - Unknown), DOLICALCIFEROL] (C - Product used for unknown indication - na - [na] - na - Unknown), FERROUS GLUCONATE] (C - Product used for unknown indication - na - [na] - na - Unknown), FLUTICASON PROPRIONATE] (C - Product used for unknown indication - na - [na] - na - Unknown), GLYCERYL TRINOTRATE] (C - Product used for unknown indication - na - [na] - na - Sublingual), LUSKOPRIL, LUSKOPRIL DIHYDRATE] (C - Product used for unknown indication - na - [na] - na - Unknown), MACRODOL 3300] (C - Product used for unknown indication - na - [na] - na - Unknown), MAGNESIUM HYDROXIDE] (C - Product used for unknown indication - na - [na] - na - Unknown), METHYL, CAMPHOR, METHYL SALICYLATE] (C - Product used for unknown indication - na - [na] - na - Unknown), METOPROLOL, SULCONATE] (C - Product used for unknown indication - na - [na] - na - Unknown), DINDANETRON] (C - Product used for unknown indication - na - [na] - na - Unknown), SPRONOLACTONE] (C - Product used for unknown indication - na - [na] - na - Unknown), TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - Unknown)	CSR
EU-EC-1000758161	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Blood lactate acid increased (14 - Fatal - Results in Death, Caused Prolonged Hospitalisation), Bradycardia (14 - Fatal - Results in Death, Caused Prolonged Hospitalisation), Cardiac arrest (14 - Fatal - Results in Death, Caused Prolonged Hospitalisation), Death (14 - Fatal - Results in Death, Caused Prolonged Hospitalisation), Heart sounds abnormal (14 - Fatal - Results in Death, Caused Prolonged Hospitalisation), Pulse absent (14 - Fatal - Results in Death, Caused Prolonged Hospitalisation), Respiration abnormal (14 - Fatal - Results in Death, Caused Prolonged Hospitalisation), Resuscitation (14 - Fatal - Results in Death, Caused Prolonged Hospitalisation), Unresponsive to stimuli (14 - Fatal - Results in Death, Caused Prolonged Hospitalisation), White blood cell count increased (14 - Fatal - Results in Death, Caused Prolonged Hospitalisation)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (C - Product used for unknown indication - na - [na] - na - na), AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Product used for unknown indication - Unknown - [na] - 5mg - Unknown), BISOPROLOL, BISOPROLOL FLUMARATE, BISOPROLOL, HEMIFLUMARATE] (C - Product used for unknown indication - Unknown - [na] - 10mg - Unknown), FURSEMIDE] (C - Product used for unknown indication - Unknown - [na] - 50mg - Unknown), BISBORONIC DINATRATE] (C - Product used for unknown indication - Unknown - [na] - 30mg - Unknown), LEVOTHYRONINE, LEVOTHYRONINE SODIUM] (C - Product used for unknown indication - Unknown - [na] - 275mg - Unknown), PARACETAMOL] (C - Product used for unknown indication - Unknown - [na] - 3000mg - Oral), SALINE, SODIUM CHLORIDE] (C - Product used for unknown indication - Unknown - [na] - na - Unknown), CLOPIDOGREL, HYDROGEN SULFATE [CLOPIDOGREL, HYDROGEN SULFATE] (C - Product used for unknown indication - na - [na] - na - Unknown), ASCORBIC ACID, ZINC, COPPER, RETINOL, ALPHA-TOCOPHEROL] (C - Product used for unknown indication - na - [na] - na - Unknown), DOLICALCIFEROL] (C - Product used for unknown indication - na - [na] - na - Unknown), FERROUS GLUCONATE] (C - Product used for unknown indication - na - [na] - na - Unknown), FLUTICASON PROPRIONATE] (C - Product used for unknown indication - na - [na] - na - Unknown), GLYCERYL TRINOTRATE] (C - Product used for unknown indication - na - [na] - na - Sublingual), LUSKOPRIL, LUSKOPRIL DIHYDRATE] (C - Product used for unknown indication - na - [na] - na - Unknown), MACRODOL 3300] (C - Product used for unknown indication - na - [na] - na - Unknown), MAGNESIUM HYDROXIDE] (C - Product used for unknown indication - na - [na] - na - Unknown), METHYL, CAMPHOR, METHYL SALICYLATE] (C - Product used for unknown indication - na - [na] - na - Unknown), METOPROLOL, SULCONATE] (C - Product used for unknown indication - na - [na] - na - Unknown), DINDANETRON] (C - Product used for unknown indication - na - [na] - na - Unknown), SPRONOLACTONE] (C - Product used for unknown indication - na - [na] - na - Unknown), TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - Unknown)	CSR
EU-EC-1000758160	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000758159	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000758158	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Malaise (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000758157	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Anal incontinence (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Hypotonia (14 - Fatal - Results in Death), Unresponsive to stimuli (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	ACEFYSALICYLIC ACID] (C - Product used for unknown indication - na - [na] - 81mg - na), FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - na - [na] - 20mg - na), LEVOTHYRONINE, LEVOTHYRONINE SODIUM] (C - Product used for unknown indication - na - [na] - na - na), PARACETAMOL] (C - Product used for unknown indication - na - [na] - 325mg - Unknown), BENZODIOL B] (C - Product used for unknown indication - na - [na] - 8.5mg - na), GABAPENTIN] (C - Product used for unknown indication - na - [na] - 3000mg - Unknown), HYDROCODONE BITARTRATE, PARACETAMOL] (C - Product used for unknown indication - na - [na] - na - Unknown), TORASEMIDE] (C - Product used for unknown indication - na - [na] - 100mg - Oral), VALSARTAN] (C - Product used for unknown indication - na - [na] - na - Oral), WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - na - [na] - 4mg - Unknown)	CSR
EU-EC-1000758156	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	AMLODIPINE BESILATE] (C - Hyperperistalsis - na - [na] - 10mg - Oral), INSULIN, INSULIN HUMAN] (C - Diabetes mellitus - na - [na] - na - Subcutaneous), PARACETAMOL] (C - Body temperature increased, Pain - na - [na] - 1300mg - Oral), ATORVASTATIN] (C - Blood phosphorus - na - [na] - na - na), METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BIF] (C - Product used for unknown indication - na - [na] - na - na)	CSR
EU-EC-1000758155	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Dyspnoea (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	CYMBALTA [DULOXETINE, DULOXETINE HYDROCHLORIDE] (C - na - na - [na] - na - na), KEPPRA [LEVETIRACETAM] (C - na - na - [na] - na - na), AMODARONE, AMODARONE HYDROCHLORIDE] (C - na - na - [na] - na - na), ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - na - na - [na] - na - na), CARVEDILOL] (C - na - na - [na] - na - na), CICLONIDE] (C - na - na - [na] - na - na), GUAFENESIN] (C - na - na - [na] - na - na), IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - na - na - [na] - na - na), LEVOTHYRONINE, LEVOTHYRONINE SODIUM] (C - na - na - [na] - na - na), MEGESTROL ACETATE] (C - na - na - [na] - na - na), MOMIFLUMATE] (C - na - na - [na] - na - na), DMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - na - na - [na] - na - na), POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - na - na - [na] - na - na), PREDNISON] (C - na - na - [na] - na - na), RIFAMPICIN] (C - na - na - [na] - na - na), RISUALFATE] (C - na - na - [na] - na - na), SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - na - na - [na] - na - na), CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - na - na - [na] - na - na), TLACTASE] (C - Product used for unknown indication - na - [na] - na - na)	CSR
EU-EC-1000758154	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Erythema (14 - Unknown -), Localised oedema (14 - Unknown -), Skin warm (14 - Unknown -)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	ELIGUS [APIXABAN] (C - Product used for unknown indication - na - [na] - na - Unknown), AMODARONE HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - Unknown), CARVEDILOL] (C - Product used for unknown indication - na - [na] - na - Unknown), FERROUS SULFATE] (C - Product used for unknown indication - na - [na] - na - Unknown)	CSR
EU-EC-1000758153	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), X-ray with contrast (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000758152	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	ELIGUS [APIXABAN] (C - Product used for unknown indication - na - [na] - na - Unknown), ASCORBIC ACID, CALCIUM GLUBONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - Product used for unknown indication - na - [na] - na - na), AZELASTINE] (C - Product used for unknown indication - na - [na] - na - Unknown), FANTONIEN] (C - Product used for unknown indication - na - [na] - na - Unknown), FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - Unknown), FUROSEMIDE, FUROSEMIDE SODIUM] (C - Product used for unknown indication - na - [na] - na - Unknown), MAGNESIUM OXIDE] (C - Product used for unknown indication - na - [na] - na - Unknown), METOPROLOL, TARTRATE] (C - Product used for unknown indication - na - [na] - na - Unknown), MONTELUKAST, MONTELUKAST SODIUM] (C - Product used for unknown indication - na - [na] - na - Unknown), DMEPRAZOLE] (C - Product used for unknown indication - na - [na] - na - Unknown), POTASSIUM, POTASSIUM CHLORIDE, POTASSIUM GLYCEROPHOSPHATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM HYDROGEN TARTRATE] (C - Product used for unknown indication - na - [na] - na - na), SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - na - [na] - na - Unknown), TERAZOSIN, TERAZOSIN HYDROCHLORIDE DIHYDRATE] (C - Product used for unknown indication - na - [na] - na - Unknown)	CSR
EU-EC-1000758151	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Dyspepsia (14 - Fatal - Results in Death, Other Medically Important Condition), Ruralis labris (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000758150	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Adhesis (14 - Fatal - Results in Death), COVID-19 (14 - Fatal - Results in Death), Cough (14 - Fatal - Results in Death), Death (14 - Fatal - Results in Death), Endotracheal intubation (14 - Fatal - Results in Death), Hemiparesis (14 - Fatal - Results in Death), Respiratory failure (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000758149	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000758148	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Acute respiratory failure (85 - Fatal - Results in Death, Caused Prolonged Hospitalisation, Other Medically Important Condition), Death (14 - Fatal - Results in Death, Caused Prolonged Hospitalisation, Other Medically Important Condition), Hypoxia (85 - Fatal - Results in Death, Caused Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	CELLCEP [MYCOPHENOLATE MOFETIL] (C - Product used for unknown indication - na - [na] - na - Unknown), ZYREXA [OLANZAPINE] (C - Product used for unknown indication - na - [na] - na - Unknown), ATOVAGUONE] (C - Product used for unknown indication - na - [na] - na - Unknown), CARVEDILOL] (C - Product used for unknown indication - na - [na] - na - Unknown), CICLONIDE] (C - Product used for unknown indication - na - [na] - na - Respiratory (inhalation)), ELETIMBE] (C - Product used for unknown indication - na - [na] - na - Unknown), ELETIMBE] (C - Product used for unknown indication - na - [na] - na - Unknown), FENICARFENATE, FENICARFENATE NANONISED] (C - Product used for unknown indication - na - [na] - na - Unknown), LEVOSULBUTAMOL, HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - Respiratory (inhalation)), MACRODOL 3300] (C - Product used for unknown indication - na - [na] - na - Unknown), DMEPRAZOLE, OMEPRAZOLE MAGNESIUM] (C - Product used for unknown indication - na - [na] - na - Unknown), PAROXETINE, PAROXETINE HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - Unknown), PREDNISON] (C - Product used for unknown indication - na - [na] - na - Unknown), TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - Unknown), LUMICLONUM] (C - Product used for unknown indication - na - [na] - na - Unknown)	CSR
EU-EC-1000758147	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000758146	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000758145	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	KETOCOANAZOLE [KETOCOANAZOLE] (C - Product used for unknown indication - na - [na] - na - na), LEVEMIR [INSULIN DETEMIR] (C - Product used for unknown indication - na - [na] - na - na), LEVETIRACETAM [LEVETIRACETAM] (C - Product used for unknown indication - na - [na] - na - na), PROLIA [DENOSUMAB] (C - Product used for unknown indication - na - [na] - na - na), MIRA [ACICLOVIR] (C - Product used for unknown indication - na - [na] - na - na), MIRA [ACICLOVIR] (C - Product used for unknown indication - na - [na] - na - na), PARACETAMOL] (C - Product used for unknown indication - na - [na] - na - na), PARACETAMOL] (C - Product used for unknown indication - na - [na] - na - na), CALCIUM CARBONATE] (C - Product used for unknown indication - na - [na] - na - na), CARBOHYDRATES NOS] (C - Product used for unknown indication - na - [na] - na - na), DOLICALCIFEROL] (C - Product used for unknown indication - na - [na] - na - na), DOUSATE] (C - Product used for unknown indication - na - [na] - na - na), FATS NOS] (C - Product used for unknown indication - na - [na] - na - na), FIBRE, DIETARY] (C - Product used for unknown indication - na - [na] - na - na), FLUOXAMINE MALEATE] (C - Product used for unknown indication - na - [na] - na - na), INSULIN ASPART] (C - Product used for unknown indication - na - [na] - na - na), LORATADINE] (C - Product used for unknown indication - na - [na] - na - na), LUBIPROSTONE] (C - Product used for unknown indication - na - [na] - na - na), MACRODOL 3300] (C - Product used for unknown indication - na - [na] - na - na), MINERALS NOS] (C - Product used for unknown indication - na - [na] - na - na), POLYCARBOPHIL, CALCIUM] (C - Product used for unknown indication - na - [na] - na - na), SILICUM SULFIDE] (C - Product used for unknown indication - na - [na] - na - na), TITANINE NOS] (C - Product used for unknown indication - na - [na] - na - na)	CSR
EU-EC-1000758144	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (14 - Fatal - Results in Death), Syncope (14 - Unknown - Other Medically Important Condition)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	Not reported	CSR
EU-EC-1000758143	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (14 - Fatal - Results in Death), Unresponsive to stimuli (14 - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [na] - 1[Df] - Intramuscular)	DIXOCODONE, DIXOCODONE HYDROCHLORIDE] (C - Product used for unknown indication - na - [na] - na - na), AMLODIPINE, AMLODIPINE BESILATE] (C - Product used for unknown indication - na - [na] - na - na)	CSR

EU Local Number	EV Gateway Review Date	Report Type	Primary Source Qualification	Primary Source Country Regulatory Purpose	Literature Reference	Patient Age Group	Patient Age (as per reporter)	Patient Sex	Patient Chrg Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspecting Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - Duration - Dose - Route)	ICSR Form
												ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE) (C - Product used for unknown indication - n/a -), (BENZOTROPINE MESILATE) (C - Product used for unknown indication - n/a -), (HYDROCHLOROTHIAZIDE, TRAMETERENE) (C - Product used for unknown indication - n/a -), (LITHIUM) (C - Product used for unknown indication - n/a -), (PALIPERDONE PALMITATE) (C - Product used for unknown indication - n/a -), (PANTOPRAZOLE, PANTOPRAZOLE SODIUM) (C - Product used for unknown indication - n/a - n/a - n/a), (HYDROCODONE) (C - Product used for unknown indication - n/a - n/a - Unknown), (MIRTAZAPINE) (C - Product used for unknown indication - n/a - n/a - Unknown), (QUETIAPINE, QUETIAPINE FUMARATE) (C - Product used for unknown indication - n/a - n/a - Unknown)	
EU-EC-10007562136	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-10007562000	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-10007562098	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-10007562787	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	16-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-10007561666	08/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 MRNA VACCINE MODERNA (CX-024414) (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	RANOLAZINE, RANOLAZINE) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (ATORVASTATIN) (C - Product used for unknown indication - n/a - [n/a - 40mg - n/a]), (BIOTIN) (C - Product used for unknown indication - n/a - [n/a - 2500mg - n/a]), (CICLOSPORIN) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]), (EZETIMIBE) (C - Product used for unknown indication - n/a - [n/a - 10mg - n/a]), (FIBR OLS) (C - Product used for unknown indication - n/a - [n/a - 1000mg - n/a]), (GABAPENTIN) (C - Product used for unknown indication - n/a - [n/a - 200mg - n/a]), (LYSINE HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), (METOPROLOL, TARTRATE) (C - Product used for unknown indication - n/a - [n/a - 100mg - n/a]), (DIMEPRIZOLE, DIMEPRIZOLE MAGNESIUM) (C - Product used for unknown indication - n/a - [n/a - 20mg - n/a]), (ZINC, CALCIUM, MAGNESIUM) (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	
EU-EC-10007531480	05/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	SPRIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-10007531446	05/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Anxiety (n/a - Unknown -), Death (1d - Fatal - Results in Death), Pyrexia (n/a - Unknown -), Respiratory distress (n/a - Unknown - Other Medically Important Condition)	SPRIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-10007531480	05/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	SPRIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])	(PARACETAMOL) (C - Product used for unknown indication - Unknown -)	ICSR
EU-EC-10007532099	05/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	SPRIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-10007486510	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Recovered/Resolved -), Pain (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	SPRIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Unknown - [n/a - 1(DP) - Intramuscular])	(ACETYLSALICYLIC ACID) (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), (ATORVASTATIN) (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), (CLOSTACOL) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (OLMEPRIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), (LISINAPRIL, LISINAPRIL DIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), (METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BIF) (C - Product used for unknown indication - n/a - [n/a - n/a - Oral]), (PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), (THAMAZOLE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	
EU-EC-10007471030	29/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Blood creatinine increased (n/a - Unknown - Other Medically Important Condition), Blood urea increased (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Erythema (n/a - Unknown -), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Leukocytosis (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -), Respiratory rate increased (n/a - Unknown - Other Medically Important Condition)	SPRIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-10007400884	28/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Fatigue (n/a - Unknown -)	SPRIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Unknown - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-10007400892	28/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	SPRIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR
EU-EC-10007418506	24/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (0d - Fatal - Results in Death)	SPRIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 3(n) - Intramuscular])	(ESCITALOPRAM) (C - n/a - n/a - [n/a - 1(DP) - Unknown]), (FAMOTIDINE) (C - n/a - n/a - [n/a - 20mg - Unknown]), (METFORMIN HYDROCHLORIDE) (C - n/a - n/a - [n/a - 500mg - Unknown]), (PHENOBARBITAL) (C - n/a - n/a - [n/a - 1(DP) - Unknown])	ICSR
EU-EC-10007416329	23/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Erythema (n/a - Unknown -), Feeling hot (n/a - Unknown -), Swelling (n/a - Unknown -)	SPRIKEVAX (COVID-19 MRNA VACCINE MODERNA (CX-024414)) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DP) - Intramuscular])		ICSR