Time run: 07/05/2021 2	Line Listing Report Time run: 07/05/2021 22:20:28													
EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primar Source Count for Regula Purpo	e R	terature eferenc	Patien e Age Group	Ag Gr (as	atient ge oup s per porter)	Patient Sex	Parer Child Repo	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-10008490280	30/04/2021	Spontaneous	Healthcare Professiona		ean a	ot vailable	Not Specif	ried Sp		Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Hospitalisation (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	Not reported ICSR
EU-EC-10008490499	30/04/2021	Spontaneous	Healthcare Professiona	Non		ot vailable	65-85 Years		derly	Male	No	Death (n/a - Fatal - Results in Death),	n/a - Unknown])  COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE	PIOGLITAZONE [PIOGLITAZONE] (C - Type 2 diabetes mellitus - n/a - [n/a - 30mg - Oral]),
				Econo Area	mic							Myocardial infarction (n/a - Fatal - Results in Death)	JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	[AMLODIPINE, AMLODIPINE BESILATE] (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]),  [ATORVASTATIN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral]),
														[BUMETANIDE] (C - Peripheral swelling - n/a - [n/a - 1mg - Oral]),  [BUMETANIDE] (C - Type 2 diabetes mellitus - n/a - n/a - n/a]),
														[LISINOPRIL, LISINOPRIL DIHYDRATE] (C - Essential hypertension - n/a - [30d - 40mg - Oral]),  [METFORMIN HYDROCHLORIDE, GLIPIZIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral])
EU-EC-10008492328	30/04/2021	Spontaneous	Healthcare Professional		ean a	ot vailable	18-64 Years		lult	Male	No	Back pain (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),  Condition aggravated (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	Not reported ICSR
				Area								Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),  Gait disturbance (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),	n/a - Unknown])	
												Guillain-Barre syndrome (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),  Muscular weakness (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),		
												Pain (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation),  Paraesthesia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)		
EU-EC-10008492391	30/04/2021	Spontaneous	Healthcare Professiona		ean a	ot vailable	65-85 Years		derly	Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	[FAMOTIDINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),  [WARFARIN, WARFARIN SODIUM] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])
EU-EC-10008492415	30/04/2021	Spontaneous		Area		ot	65-85		derly	Female	e No	Death (n/a - Fatal - Results in Death, Life Threatening),	Immunisation - Not applicable - [n/a - n/a - Intramuscular])  COVID-19 VACCINE JANSSEN	METHOTREXATE [METHOTREXATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),
			Healthcare Professiona			vallable	Years					Pneumonia (n/a - Unknown - Results in Death, Life Threatening),  Pulmonary embolism (n/a - Unknown - Results in Death, Life Threatening),	(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [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]),  [FOLIC ACID] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),
												Thrombosis (n/a - Fatal - Results in Death, Life Threatening)		[HYDRALAZINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),  [HYDROXYCHLOROQUINE] (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]),
EU-EC-10008492669	30/04/2021	Spontaneous			ean a	ot vailable	18-64 Years		lult	Female	e No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition),  Thrombosis (n/a - Unknown - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	[LISINOPRIL, LISINOPRIL DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])  Not reported  ICSR
EU-EC-10008492675	30/04/2021	Spontaneous	Healthcare Professiona			ot vailable	More than 8 Years	5	derly	Female	e No	Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	n/a - Unknown])  COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	IRON [IRON] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])
EU-EC-10008492676	30/04/2021	Spontaneous		Area	N	ot	65-85		derly	Male	No	Death (n/a - Fatal - Results in Death),	Immunisation - Not applicable - [n/a - n/a - Unknown])  COVID-19 VACCINE JANSSEN	Not reported ICSR
			Professiona	Econo Area		vailable	Years					Thrombosis (n/a - Fatal - Results in Death)	(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	
EU-EC-10008492730	30/04/2021	Spontaneous	Healthcare Professiona	Econo	ean a	ot vailable	65-85 Years		derly	Female	e No	Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation),  Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
EU-EC-10008492885	30/04/2021	Spontaneous	Healthcare Professiona	Area Non	N		65-85 Years		derly	Female	e No	Headache (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation)  Death (n/a - Fatal - Results in Death),	Immunisation - Not applicable - [n/a - n/a - Unknown])  COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE	MELATONIN [MELATONIN] (C - Product used for unknown indication - n/a - [n/a - 5mg - Oral]),
			Professiona	Econo Area		vallable	Years					Intensive care (n/a - Fatal - Results in Death),  Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death),	JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 40mg - Oral]),  XARELTO [RIVAROXABAN] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral]),
												Pain in extremity (n/a - Fatal - Results in Death),  Thrombosis (n/a - Fatal - Results in Death)		[AMIODARONE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 100mg - Oral]),  [CALCIPOTRIOL] (C - Product used for unknown indication - n/a - [n/a - n/a - Topical]),
												This massis (wa Taliai Resalt)		[CARVEDILOL] (C - Blood pressure abnormal - n/a - [n/a5mg - Oral]),
														[COLECALCIFEROL] (C - Vitamin supplementation - n/a - [n/a - 25ug - Oral]),  [CYANOCOBALAMIN, VITAMIN B12] (C - Vitamin supplementation - n/a - [n/a - 100ug - Oral]),
														[FISH OIL] (C - Nutritional supplementation - n/a - [n/a - 1000mg - Oral]),  [FORMOTEROL FUMARATE, GLYCOPYRRONIUM, BUDESONIDE] (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 - 5mg - Oral]),  [GLYCERYL TRINITRATE] (C - Chest pain - n/a - [n/a4mg - Oral]),
														[LEVOSALBUTAMOL] (C - Dyspnoea - n/a - [n/a - n/a]), [LIDOCAINE, LIDOCAINE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - n/a - Other]),
														[LOPERAMIDE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 2mg - Oral]),  [LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 25mg - Oral]),
														[ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 4mg - Oral]),
														[POTASSIUM CHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 10meq - Oral]),  [ROPINIROLE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 2mg - Oral]),
														[ROPINIROLE, ROPINIROLE HYDROCHLORIDE] (C - Product used for unknown indication - n/a - [n/a - 1mg - Oral]),  [SALBUTAMOL SULFATE] (C - Dyspnoea - n/a - [n/a - 3mL - n/a]),
														[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a]),
FILEO 40000402022	20/04/2024	Sportonoous	Non	Non	N	ot	Not	Ad	114	Mala	No	Advance reaction /n/s. Helmours. Deculte in Decth)	COVID 40 VACCINE IANGSEN	[THIOCTIC ACID] (C - Product used for unknown indication - n/a - [n/a - 200mg - Oral]),  [TORASEMIDE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral])
EU-EC-10008492933	30/04/2021	Spontaneous	Non Healthcare Professiona		ean a		Not Specif		iuit	Male	No	Adverse reaction (n/a - Unknown - Results in Death),  Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	Not reported ICSR
EU-EC-10008492977	30/04/2021	Spontaneous			ean a	ot vailable	Not Specif	ied Sp			e No	Death (n/a - Fatal - Results in Death)	n/a - Unknown])  COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
EU-EC-10008493867	30/04/2021	Spontaneous	Healthcare	Area	N		18-64		lult	Male	No	Cardiac arrest (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation),	Immunisation - Not applicable - [n/a - n/a - Unknown])  COVID-19 VACCINE JANSSEN	EMTRICITABINE, TENOFOVIR ALAFENAMIDE, RILPIVIRINE [EMTRICITABINE, TENOFOVIR ALAFENAMIDE, RILPIVIRINE] (C - Product used for unknown ICSR
			Professiona	Econo Area		vallable	Years					Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Dyspnoea (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation),	JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	indication - n/a - [n/a - n/a - Unknown]),  METHOTREXATE [METHOTREXATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]),
												Urinary tract infection (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation)		[CEFEPIME] (C - Product used for unknown indication - n/a - [7d - 2g - Unknown]),  [GABAPENTIN] (C - Product used for unknown indication - n/a - [n/a - 600mg - Unknown]),
														[GLIPIZIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - n/a - Unknown]),  [HYDROMORPHONE HYDROCHLORIDE] (C - Pain - n/a - [n/a - 2mg - Unknown]),
														[INSULIN, INSULIN HUMAN] (C - Type 2 diabetes mellitus - n/a - [n/a - n/a - Unknown]),  [METOPROLOL, METOPROLOL TARTRATE] (C - Product used for unknown indication - n/a - [n/a - 25mg - n/a]),
														[MIRTAZAPINE] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), [NITROFURANTOIN] (C - Product used for unknown indication - n/a - [n/a - 100mg - Unknown])
EU-EC-10008493881	30/04/2021	Spontaneous	Healthcare Professiona	Econo			65-85 Years		derly	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death),	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	[ACETYLSALICYLIC ACID, ASPIRIN BP] (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])
				Area								Myocardial infarction (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	Immunisation - Not applicable - [n/a - n/a - Intramuscular])	
EU-EC-10008494042	30/04/2021	Spontaneous	Healthcare Professiona				65-85 Years		derly	Female	e No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
EU-EC-10008494053	30/04/2021	Spontaneous	Healthcare Professiona	Non Europ	ean a	ot vailable		5	derly	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition),	Immunisation - Not applicable - [n/a 5mL - Unknown])  COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE	Not reported ICSR
				Econo Area			Years					Tremor (n/a - Unknown - Results in Death, Other Medically Important Condition)	JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	
EU-EC-10008494607	30/04/2021	Spontaneous			ean a	ot vailable	Not Specif	ried Sp		Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition),  Malaise (n/a - Unknown - Results in Death, Other Medically Important Condition),	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	Not reported ICSR
EU-EC-10008494983	30/04/2021	Spontaneous	Healthcare				65-85 Years		derly	Female	e No	Unresponsive to stimuli (n/a - Unknown - Results in Death, Other Medically Important Condition)  Death (n/a - Fatal - Results in Death, Other Medically Important Condition),	n/a - Unknown])  COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE	Not reported ICSR
			Professiona	Area	mic							Dizziness (n/a - Unknown - Results in Death, Other Medically Important Condition),  Headache (n/a - Recovered/Resolved - Results in Death, Other Medically Important Condition),	JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	
												Hypertension (0d - Recovered/Resolved - Results in Death, Other Medically Important Condition),  Vomiting (n/a - Unknown - Results in Death, Other Medically Important Condition)		
EU-EC-10008479778	29/04/2021	Spontaneous	Non Healthcare Professiona		ean a	ot vailable	18-64 Years		lult	Male	No	Asthenia (n/a - Unknown - Results in Death),  Confusional state (n/a - Not Recovered/Not Resolved - Results in Death),	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	Not reported ICSR
				71100								Death (n/a - Fatal - Results in Death),  Heart rate increased (n/a - Unknown - Results in Death),	n/a - Unknown])	
												Influenza like illness (n/a - Unknown - Results in Death),  Respiratory rate increased (n/a - Unknown - Results in Death)		
EU-EC-10008479790	29/04/2021	Spontaneous	Healthcare Professiona	Econo	ean a	ot vailable	65-85 Years		derly	Female	No	Acute respiratory failure (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Oth Medically Important Condition),	(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
				Area								Arthralgia (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Cerebrovascular accident (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important	Immunisation - Not applicable - [n/a - n/a - Intramuscular])	
												Condition),  Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
												Encephalopathy (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
												Hemiparesis (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Malaise (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically		
												Important Condition),  Respiratory acidosis (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),		
												Medically Important Condition),  Urinary tract infection (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC-10008479984	29/04/2021	Spontaneous		al Econo		ot vailable	65-85 Years		derly	Male	No	Cerebrovascular accident (n/a - Fatal - Results in Death),  Death (n/a - Fatal - Results in Death),	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
EU-EC-10008480202	29/04/2021	Spontaneous		Non Europ		ot vailable	18-64 Years	1 -	lult	Male	No	Thrombosis (n/a - Fatal - Results in Death)  Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	Immunisation - Not applicable - [n/a - n/a - Intramuscular])  COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE	Not reported ICSR
			Professiona			avit	. Jais					Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Gait inability (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	
												Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Impaired driving ability (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),		
												Loss of consciousness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),		
	I	1										Mechanical ventilation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	1	

EU Local Number EV Gateway	Report Type	Source	Primary Source	Literature Reference	Age	Age	Patient Sex	Child	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken -	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])  ICSR Form
Receipt Date		Qualification	for Regulatory Purposes	,		Group (as per reporter)		Report		[Duration - Dose - Route])	
									Muscle spasms (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),		
FU FC 40000404080 20/04/2024	Chantanasus	Llookhoore	Non	Not	18-64	A dult	Famala	No	Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID 40 VACCINE JANGSEN	Net reported
EU-EC-10008481288 29/04/2021	Spontaneous	Professional	European Economic	Not available		Adult	Female	NO	Bradycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
			Area						Disseminated intravascular coagulation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	Immunisation - Not applicable - [n/a - n/a - Intramuscular])	
									Endotracheal intubation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Haemodialysis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),		
									Hypotension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),		
									Liver function test increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Mental status changes (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),		
									Metabolic acidosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),		
									Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),		
									SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),		
									Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),		
EU-EC-10008463647 28/04/2021	Spontaneous	Non	Non	Not	18-64	Adult	Female	No	Transfusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)  COVID-19 (n/a - Unknown - Results in Death, Other Medically Important Condition),	COVID-19 VACCINE JANSSEN	Not reported ICSR
20/04/2021	Opernaneous	Healthcare Professional	European	available	.	rtauit	Cinale		Death (n/a - Fatal - Results in Death, Other Medically Important Condition),	(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	The reported
EU-EC-10008464223 28/04/2021	Spontaneous	Non	Non	Not	65-85	Elderly	Female		Foaming at mouth (n/a - Unknown - Results in Death, Other Medically Important Condition)  Death (n/a - Fatal - Results in Death)	n/a - Unknown])  COVID-19 VACCINE JANSSEN	Not reported ICSR
		Healthcare Professional		available	Years					(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	
EU-EC-10008464363 28/04/2021	Spontaneous		Non European	Not available		Adult	Female	No	Death (n/a - Fatal - Results in Death)	n/a - Unknown])  COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE	Not reported ICSR
		Professional	Economic Area							JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	
EU-EC-10008464652 28/04/2021	Spontaneous	Healthcare Professional	Non European Economic		Not Specified		Male	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
EU EO 10022 IS	0	NI-	Area	N	40.5:	A at the	N.4 - 1		Parkardia (n/a Nat Parana d'Alai Parana d'Al	Immunisation - Not applicable - [n/a - n/a - Unknown])	Not apported.
EU-EC-10008464653 28/04/2021	spontaneous	Non Healthcare Professional	Economic	Not available		Adult	Male	No	Back pain (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition),  Death (n/a - Fatal - Results in Death, Other Medically Important Condition),	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
			Area						Epistaxis (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition),	Immunisation - Not applicable - [n/a - n/a - Unknown])	
									Haemoptysis (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition),  Increased viscosity of upper respiratory secretion (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important		
									Condition), Secretion discharge (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition),		
EU-EC-10008468700 28/04/2021	Spontaneous		Non	Not		Adult	Male	No	Thrombosis (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition)  Death (n/a - Fatal - Results in Death),	COVID-19 VACCINE JANSSEN	Not reported ICSR
		Healthcare Professional	European Economic Area	available	Years				Malaise (n/a - Unknown - Results in Death)	(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	
EU-EC-10008458687 27/04/2021	Spontaneous	Healthcare Professional		Not available		Adult	Female	No	Death (n/a - Fatal - Results in Death),	n/a - Unknown])  COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE	[LOSARTAN, LOSARTAN POTASSIUM] (C - Product used for unknown indication - n/a - [n/a - n/a])
		T TOTOGOTOTIA	Economic Area	availabio	, sais				Haemorrhagic stroke (n/a - Fatal - Results in Death)	JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	
EU-EC-10008441557 26/04/2021	Spontaneous	Healthcare		Not available			Not Specified		Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE	Not reported ICSR
		Professional	Area							JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	
EU-EC-10008441930 26/04/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
EU-EC-10008411791 23/04/2021	Spontaneous	Healthcare	Area			Elderly	Female	No	Capillary leak syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	Immunisation - Not applicable - [n/a - n/a - Unknown])  COVID-19 VACCINE JANSSEN	[AMITRIPTYLINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a]),
		Professional	European Economic Area	available	Years				Condition aggravated (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	[LISINOPRIL, LISINOPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a]),
									Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Disseminated intravascular coagulation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	n/a - Intramuscular])	[SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [TERBUTALINE] (C - n/a - n/a - n/a - n/a]),
									Distributive shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),		[THEOPHYLLINE] (C - n/a - n/a - [n/a - n/a])
EU-EC-10008413601 23/04/2021	Spontaneous	Healthcare	Non European	Not available		Adult	Male	No	Renal failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)  Death (0d - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE	Not reported ICSR
		Professional	Economic Area							JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	
EU-EC-10008402410 22/04/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	Not Specified		Female	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
EU-EC-10008387135 21/04/2021	Spontaneous	Non	Area	Not	18-64	Adult	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition),	Immunisation - Not applicable - [n/a - n/a - Unknown])  COVID-19 VACCINE JANSSEN	Not reported ICSR
20 20 10000001100 210042021	Spermaneous	Healthcare Professional	European	1		rtaun	iviaio		Thrombosis (n/a - Unknown - Results in Death, Other Medically Important Condition)	(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	
EU-EC-10008388255 21/04/2021	Spontaneous	Healthcare	Non	Not	18-64 Vears	Adult	Female	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	n/a - Unknown])  COVID-19 VACCINE JANSSEN	Not reported ICSR
		Professional	European Economic Area	available	Years				Hemiplegia (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Haknown])	
EU-EC-10008358558 19/04/2021	Spontaneous	Healthcare		Not available		Adult	Female	No	Cardiac failure (n/a - Unknown - Results in Death, Other Medically Important Condition),	n/a - Unknown])  COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE	Not reported ICSR
		Professional							Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pain (n/a - Unknown - Results in Death, Other Medically Important Condition)	JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	
EU-EC-10008354029 18/04/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available			Not Specified	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
FILEC.40009405447 05/04/000	Sporter	Healthan	Area	Not	More	Elderh:	Fomel	No	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported.
EU-EC-10008195117 05/04/2021	Spontaneous	Professional	Non European Economic Area	Not available	More than 85 Years	Lidelly	i emale	INO	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),  Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	Not reported ICSR
EU-EC-10008197653 05/04/2021	Spontaneous		Non	Not		Elderly	Female	No	Atrial fibrillation (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	n/a - Unknown])  COVID-19 VACCINE JANSSEN	Not reported ICSR
		Healthcare Professional		available	than 85 Years				Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	
									Dysphagia (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),  Hypotension (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	n/a - Unknown])	
EU-EC-10008164806 01/04/2021	Spontaneous	Non	Non				Male	No	Peripheral embolism (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)  COVID-19 (n/a - Unknown - Results in Death, Other Medically Important Condition),	COVID-19 VACCINE JANSSEN	Not reported ICSR
		Healthcare Professional		available	Specified				Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	
EU-EC-10008152972 31/03/2021	Spontaneous	Healthcare	Non European		Not I Specified	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	n/a - Unknown])  COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE	Not reported ICSR
		Professional	Economic Area							JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	
EU-EC-10008135660 30/03/2021	Spontaneous			Not available	Not Specified		Female		Death (n/a - Fatal - Results in Death), Pain in extremity (n/a - Unknown - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S -	Not reported ICSR
EU-EC-10008138926 30/03/2021	Spontanceur		Area	Not	18-64	Adult	Female		Abdominal pain upper (n/a - Unknown - Results in Death),	Immunisation - Not applicable - [n/a - n/a - Unknown])  COVID-19 VACCINE JANSSEN	Not reported ICSR
	Sportaneous	Professional	European Economic Area			suit	. Jinale		Death (n/a - Fatal - Results in Death),	(AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a -	ICSR
									Ear pain (n/a - Unknown - Results in Death), Fatigue (n/a - Unknown - Results in Death),	n/a - Unknown])	
									Headache (n/a - Unknown - Results in Death),		
									Pain in extremity (n/a - Unknown - Results in Death), Pallor (n/a - Unknown - Results in Death),		
									Pre-existing condition improved (n/a - Unknown - Results in Death)		