## Line Listing Report Time run: 30/11/2022 10:07:17

EU Local Number	EV Gateway Receipt Date		Primary Source Qualification	Primary Source Country for Regulatory	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	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])	ICSI Forr
EU-EC- 10010885473	07/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010885602	07/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										(n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010885802	07/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),		COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010886126	07/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash pruritic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010886234	07/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not		[PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Ear infection - n/a - [n/a - n/a - Oral]),	ICS
										Recovered/Not Resolved - )		[TRIMETHOPRIM] (C - Urinary tract infection - n/a - [n/a - n/a - Oral])	
EU-EC- 10010886457	07/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC-	07/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	(n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10010886462	07,11,1011	эролагизэцэ		Economic Area	available	Years	, as course	, sindle		Unknown - Other Medically Important Condition),	(S - n/a - n/a - [n/a - n/a - Intramuscular])	Петорогея	100
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010886465	07/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010886509	07/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC-	06/12/2021	Cnonton	Non	Europa	Not	10 17	Not	Female	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIDNATY FTOTINAMED AND	Not reported	ICC
10010862576	00/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Specified	remale	INU	Chest discomfort (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Fatigue (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			

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											erythema (n/a - Not Recovered/Not Resolved - ),			
											Injection site inflammation (n/a - Not Recovered/Not Resolved - ),			
											Injection site pain (n/a - Not Recovered/Not Resolved - ),			
											Injection site warmth (n/a - Not Recovered/Not Resolved - ),			
											Malaise (n/a - Not Recovered/Not Resolved - ),			
											Myalgia (n/a - Not Recovered/Not Resolved - ),			
											Nausea (n/a - Not Recovered/Not Resolved - )			
	EU-EC- 10010862772	06/12/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Female	No	Rash (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
											Rash erythematous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Rash macular (n/a - Unknown - Other Medically Important Condition),			
											Rash pruritic (n/a - Recovering/Resolving - Other Medically Important Condition)			
	EU-EC- 10010862785	06/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male		Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
	EU-EC- 10010862796	06/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - Disabling,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Dizziness (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
											Feeling abnormal (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
											Headache (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
											Myalgia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)			
	EU-EC- 10010862891	06/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female		Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
											Seizure (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- L0010862938	06/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available		Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)			
	EU-EC- 10010862981	06/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
											Drug ineffective (n/a			

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										Recovered/Resolved Other Medically Important Condition)			
EU-EC- 10010863304	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Not Recovered/Not Resolved - )	(S - Immunisation - n/a - [n/a - n/a - n/a]), [THIAMAZOLE] (S -	[LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 50mg - n/a])	ICSR
											Basedow's disease - n/a - [n/a - 5mg - n/a])		
EU-EC- 10010863369	06/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		[[n/a - 3]] - [n/a]] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Electrocardiogram ST segment elevation (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation, Other Medically Important Condition), Pericarditis (n/a -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
EU-EC-	06/12/2021	Spontaneous	Haaltheara	Non	Not	12-17	Not	Female	No	Ventricular extrasystoles (n/a - Unknown - ) Decreased appetite	COMIRNATY [TOZINAMERAN]	Net reported	ICSR
10010864169	00/12/2021	Sportaneous		European Economic Area	available	Years	Specified	i emale	INO	(n/a - Unknown - Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSK
										Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Loss of personal independence in daily activities (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Mental fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010864173	06/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Cardiac infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010864203	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - ), Fall (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving - Other Medically Important Condition),			
										Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Malaise (n/a - Recovering/Resolving - ),			
EU-EC-	06/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Pyrexia (n/a - Recovering/Resolving - ) Anxiety (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010864233				European Economic Area	available	Years	Specified				(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Recovered/Resolved Other Medically Important Condition),			
										Hypoxia (n/a - Recovering/Resolving - Other Medically Important			

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										Condition),  Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Peripheral coldness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010864701	06/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010864704	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Swelling (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010864785	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010864880	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Back pain (n/a - Recovering/Resolving - ), Chills (2d -	Not applicable - [n/a - 30ug - n/a])		
										Recovered/Resolved - ), Nausea (2d -			
										Recovered/Resolved - ), Neck pain (n/a -			
										Recovering/Resolving			
EU-EC- 10010864955	06/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diplopia (n/a - Recovering/Resolving - ), Facial paralysis (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										- ),  Nausea (n/a - Recovering/Resolving			
										- ), Vomiting (n/a - Recovering/Resolving			
EU-EC- 10010865085	06/12/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
				Economic Area	available					Caused/Prolonged Hospitalisation, Other Medically Important Condition)	Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10010865169	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Other Medically Important Condition), Enteritis (n/a -			
										Unknown - Caused/Prolonged Hospitalisation, Other Medically			
EU-EC- 10010865192	06/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Chest discomfort (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				Area						Important Condition),  Respiration abnormal	n/a])		
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010865230	06/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Condition),			
										Condition),  Dysgeusia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important			

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										Fatigue (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Pain in extremity (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition)			
EU-EC- 10010865250	06/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Nausea (n/a - Recovered/Resolved - )			
EU-EC- 10010865281	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a -			
										Unknown - Caused/Prolonged Hospitalisation), Headache (4d -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (4d -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (4d -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010865282	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010865647	06/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haematoma (9d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10010865699	06/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anxiety (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Asthma (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation),  Chest discomfort (n/a - Not Recovered/Not Resolved -			
										Caused/Prolonged Hospitalisation),			
										Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Depression (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation),  Fatigue (n/a - Not Recovered/Not			
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EU-EC- 10010866518	U6/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Recovered/Resolved -), Rash vesicular (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	ivot reported	IC
EU-EC- 10010866471		Spontaneous	Healthcare Professional	Economic Area	Not available	12-17 Years	Adolescent		No	Fatigue (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		IC
										Injection site warmth (n/a - Unknown - ), Papule (1wk - Recovered/Resolved			
										Injection site pruritus (n/a - Unknown - ),			
										Injection site erythema (n/a - Unknown - ),	- n/a])		
:U-EC- 0010866150	06/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	IC
										Important Condition), Peak expiratory flow rate decreased (n/a -			
EU-EC- 10010865762	06/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>IC</u>
										(n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
										Resolved - Caused/Prolonged Hospitalisation), Weight decreased			
										Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not			
										Sleep disorder (n/a - Not Recovered/Not Resolved -			
										Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a -			
										Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not			
										Caused/Prolonged Hospitalisation), Myalgia (n/a - Not Recovered/Not			
										Hospitalisation),  Malaise (n/a - Not Recovered/Not Resolved -			
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Heart rate increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not			
										Hospitalisation), Haemoglobin increased (n/a - Not			

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										Recovered/Resolved			<u> </u>
EU-EC- 10010866525	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arrhythmia (7d - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Chest pain (7d - Unknown - ),			
										Pyrexia (7d - Recovering/Resolving - ),			
										Somnolence (7d - Recovering/Resolving - )			
U-EC- 0010866580	06/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICS
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
11.50	06/12/2021	Charles	Non	F. Wangan	Not	12.17	Adolescent	Fomala	No	Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIDNATY FTOZINAMEDANIA	Networked	10
:U-EC- 0010866652	06/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	remaie	No	Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
										Paraesthesia (n/a - Recovered/Resolved - ),			
										Rash (n/a - Not Recovered/Not Resolved - )			
U-EC- 0010866688	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (8d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	RELVAR ELLIPTA 184 MICROGRAMS/22 MICROGRAMS INHALATION POWDER, PRE-DISPENSED [FLUTICASONE FUROATE, VILANTEROL] (C - Asthma - n/a - [n/a - n/a - n/a]),	IC
										Dysphonia (n/a - Unknown - ), Dyspnoea (1d - Recovered/Resolved		[CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - 10mg - n/a]),	
										- Life Threatening),  Erythema (1d - Recovered/Resolved		[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - )	
										- Life Threatening),  Hypersensitivity (1d - Recovered/Resolved			
										- Life Threatening), Lip swelling (n/a - Unknown - ),			
										Rash (n/a - Unknown			
										Swollen tongue (n/a - Unknown - ),			
										Throat tightness (1d			
										Recovered/Resolved - Life Threatening)			
EU-EC- 10010867662	06/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	IC
										Hypoaesthesia (n/a - Unknown - Other Medically Important Condition),			
										Limb discomfort (1d			
										Recovered/Resolved - Other Medically Important Condition),			
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010867679	06/12/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Vision blurred (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>IC</u>

				Economic Area						Other Medically Important Condition)	Not applicable - [1d - n/a - n/a])		
:U-EC- .0010867719	06/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
:U-EC- .0010867771	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
:U-EC- 0010867792	06/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - ), Polymenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 1.0010867847	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Supraventricular tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 1.0010867954	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - ), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
:U-EC- :0010867961	06/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a – Unknown – Other Medically Important Condition), Chest pain (n/a – Unknown – Other Medically Important Condition), Cough (n/a – Not Recovered/Not Resolved – Other Medically Important Condition), Dizziness (n/a – Unknown – Other Medically Important Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICCS
EU-EC- 1.0010867964	06/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically - Other Medicall	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 1.0010867965	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS

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									Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation),			
									Vertigo (n/a - Unknown - Caused/Prolonged Hospitalisation)			
U-EC- 0010867967	06/12/2021	Spontaneous	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	IC
									Pyrexia (n/a - Unknown - )			
U-EC- 0010867978	06/12/2021	Spontaneous	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (2d - Recovered/Resolved - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	IC
									Chest pain (2d - Recovered/Resolved - Life Threatening),			
									Dyspnoea (2d - Recovered/Resolved - Life Threatening),			
									Fatigue (n/a - Unknown - Life Threatening),			
									Malaise (n/a - Unknown - Life Threatening),			
									Myalgia (n/a - Unknown - Life Threatening),			
									Myocarditis (n/a - Unknown - Life Threatening, Other Medically Important Condition)			
J-EC- 0010867991	06/12/2021	Spontaneous	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>I</u>
									Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
									Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation),			
									Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
									Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation)			
J-EC- 0010867993	06/12/2021	Spontaneous	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	1
U-EC- 0010868007	06/12/2021	Spontaneous	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood creatine phosphokinase MB increased (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	Ī
									Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation),			
									Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
									Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
									Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
									Dyspnoea (n/a -			

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											Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Troponin I abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation)			
	EU-EC- 10010868010	06/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asphyxia (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
											Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation)			
	EU-EC- 10010868257	06/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Sudden death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
	EU-EC- 10010868285	06/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - ), Encephalitis	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
											autoimmune (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	indanidacular j)		
											Generalised tonic- clonic seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Partial seizures (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
											Urticaria (n/a - Not Recovered/Not Resolved - )			
	EU-EC- 10010868306	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cluster headache (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
											Conjunctival haemorrhage (2d - Recovered/Resolved - ),			
											Eye pain (2d - Recovered/Resolved - ),			
											Headache (2d - Recovered/Resolved -), Lacrimation			
	EU-EC-	06/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	increased (2d - Recovered/Resolved - ) Cyanosis (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
	10010868323	,, 2021		Professional	Economic Area	available	Years				Recovered/Not Resolved - Other Medically Important Condition),	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
											Muscular weakness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			

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										Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010868561	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Local reaction (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010868652	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010868661	06/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition)  Chills (n/a - Recovered/Resolved - ),  Headache (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010868697	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- ) Myocardial infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	06/12/2021	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) Chest pain (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010868932			Healthcare	European Economic Area	available	Years	Specified			Fatal - Results in Death), Diabetes mellitus (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-	06/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Results in Death) Blood creatine	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010868933	06/12/2021	Spontaneous		European Economic Area	available	Years	Specified	маю	INO	phosphokinase increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMINNATY [ICZINAMIERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSK
										Myositis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010869457	06/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010869476	06/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (2d - Recovered/Resolved - ),  Vaccination site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										(2d - Recovered/Resolved - )			
EU-EC- 10010869526	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Malaise (1d - Recovered/Resolved - )			

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EU-EC- 10010869528	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Petechiae (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10010869533	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICS
										Menstrual disorder (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010869538	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10010869556	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - ), Epistaxis (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010869590	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ) Urticaria (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICS
EU-EC- 10010869657	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (3d - Recovered/Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10010869661	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010869685	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10010869704	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10010869721	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved - )  Ischaemic stroke (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL -	Not reported	ICS
EU-EC- 10010869932	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1wk - Recovered/Resolved - ), Eczema (1wk - Recovered/Resolved	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10010869940	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
										Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Dyspnoea (20min - Recovered/Resolved - Other Medically Important Condition),			
										Headache (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Lymphadenopathy (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010869943	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010870010	06/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Recovering/Resolving - )  Dysmenorrhoea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
			Professional	Area			,			Resolved - ),  Heavy menstrual bleeding (n/a - Not Recovered/Not	Not applicable - [n/a - 1{DF} - n/a])		
										Resolved - ),  Malaise (n/a - Not Recovered/Not			
										Resolved - ),  Menstruation delayed			

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										(n/a - Not Recovered/Not Resolved - ),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010870160	06/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010870168	06/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010870191	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Traumatic heart injury (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010870393	06/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<del>-</del>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010870527	06/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Vaccination site pain (1d - Recovered/Resolved			
EU-EC- 10010870547	06/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Fatigue (33d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (33d - Unknown - ), Influenza (31d - Not			
EU-EC-	06/12/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Recovered/Not Resolved - ) Hypersensitivity (n/a	TOZINAMERAN	[CETIRIZINE, CETIRIZINE	ICSR
10010870651			Healthcare Professional	European Economic Area	available	Years	Specified			- Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
										Lip swelling (n/a - Unknown - Other Medically Important Condition),			
										Pruritus (n/a - Unknown - Other Medically Important Condition),			
										Swelling face (n/a - Unknown - Other Medically Important Condition),			
										Urticaria (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010870667	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			

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										Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010870674	06/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available		Not Specified	Male	No	Autoimmune hepatitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Hepatitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Hepatitis acute (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown - )			
EU-EC- 10010870881	06/12/2021	Spontaneous	Healthcare	European Economic Area		12-17 Years	Adult	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Not Recovered/Not Resolved - ),	1,74])		
EU EC	06/12/2021	Constant	1114	Non	Note	12.17	Note	F	N.	Myalgia (n/a - Not Recovered/Not Resolved - )	COMPAND (TOTAL AMED AN	Network	TOOD
EU-EC- 10010871116	06/12/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Female	No	Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a -			
										Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010871125	06/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Pain (n/a - Unknown - Other Medically Important Condition),			
										Pericarditis (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010871128	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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El-65															
19-25															
March															
Arg			06/12/2021	Spontaneous	Healthcare Professional	Non European				Male	No	Acute disseminated		Not reported	<u>ICSR</u>
Background						Economic						(n/a - Recovering/Resolving	Not applicable - [n/a - n/a -		
Procedure   Proc												Hospitalisation,			
Europe   Part												Important			
Contract															
Conflicts)  Religions												Unknown - Other			
												Condition),			
Historian Service   Gast National (Service												Recovering/Resolving			
Recoverage (Incoming												Hospitalisation),			
Hespitalistons    Head or in the second   Head or in												Recovering/Resolving			
Cut-Ci-												Hospitalisation),			
Hadding (p)												decreased (n/a -			
EU-EC- DUILOR/134  06/12/2021 Sportnerscus Healthcare Not Prefessional Russian												Headache (n/a -			
EU-EC-   20012713-12   Got12/2021   Sportamensus   Healthcare   Non- engineering   Note   N												- Caused/Prolonged			
File-C-   Control Protection   File-C-   File-C-   Control Protection   File-C-   Fil												Hyporeflexia (n/a -			
Recovering Resolving												- Caused/Prolonged			
ELEC   10010971134   Formation of the professional Professional European Not Area   12-17 Not Residence (1) and the professional Residence (1) and the profe															
Continue												- Caused/Prolonged			
Recovering Resolving   Causely Picking   Cause															
EU-EC- 10010871336   Months												Recovering/Resolving - Caused/Prolonged			
Recovering Resolving - Caused/Frolonged - Caused/Fr															
Pâm (n/a - Unknown).  Paralysis (n/a - Recovering/Resolving - Re												Recovering/Resolving - Caused/Prolonged			
EU-EC- 10010871336   06/12/2021   Spontaneous   Healthcare   Non Professional Curopean   Not Professional Curopean   Non Healthcare   Non Professional Curopean   Non Healthcare   Non Professional Curopean   Non Healthcare   Non Professional Curopean   Non Professional Curopean   Non Healthcare   Non Healthc															
Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically EMEC- Office Medically EMEC- In 10010871134  Recovered/Resolved With Sequebe - Caused/Prolonged Hospitalisation), Pyrexia (r/a = Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (r/a = Recovering/Resolving - Caused/Prolonged Hospitalisation) Recovering/Resolving - Caused/Prolonged Hospitalisation), Pibrin D dimer Increased (r/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Urticaria (r/a = Recovering/Resolving - Caused/Prolonged Hospitalisation) - Caused/Prolonged Hospitalisation												-),			
Condition, Peresis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Peresis (n/a - Recovering/Resolving - Caused/Prolonged Hospitali												Recovering/Resolving			
EU-EC-   10010871134   Condition   Paresis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)   Pyreble (n/a - recovering/Resolving - Caused/Prolonged Hospitalisation)   Pyreble (n/a - recovering/Resolving - Caused/Prolonged Hospitalisation)   Pyreble (n/a - recovering/Resolving - Caused/Prolonged Hospitalisation)   Condition												Other Medically			
EU-EC- 10010871134 Of-12/2021 Spontaneous Healthcare Professional Real Real Real Recovering/Resolving Leaves (Na - Recovering/Resolving Leaves) (Na - Recove															
EU-EC- 10010871134  06/12/2021 Spontaneous Healthcare Professional European 10010871336  06/12/2021 Spontaneous Non Healthcare Professional European 10010871336  EU-EC- 10010871336  06/12/2021 Spontaneous Non Healthcare Professional European Professional Reversional Rev												Recovered/Resolved			
EU-EC-101087134   O6/12/2021   Spontaneous   Healthcare   Professional   European   Economic   Area   Not   Professional   European   Not   Professional   Professional   European   Not   Professional   Not   Professional   European   Not   Professional   Not   Professional   European   Not   Professional   European   Not   Professional   Not   Professional   European   Not   Professional   Not   Professional   Not   Professional   European   Not   Professional   European   Not   Professional   Not   Professional   European												Caused/Prolonged			
EU-EC- 1001087134 O6/12/2021 Spontaneous Healthcare Professional European Economic Area Not Pofessional European Economic Area Not Professional European European Economic Area Not Professional Unit Canada (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Urticaria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Urticaria Vasculitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisa															
Professional European Area Professional European Area Professional European Bullable Professional European Area Professional European Bullable Professional European Bullable Professional European Bullable Professional European Bullable Professional Bullable Professional European Bullable Professional Professional Professional Bullable Professional Bullable Professional Professional Professional Bullable Professional Professional Professional Bullable Professional Professional Professional Bullable Professional Professional Professional Professional Professional Bullable Professional Profe												- Caused/Prolonged Hospitalisation)			
Area			06/12/2021	Spontaneous		European				Female	No	increased (n/a -	(S - COVID-19 immunisation -	Not reported	ICSR
EU-EC-   10010871335   Spontaneous   Healthcare   Professional   Deliver   Professional   Spontaneous   Healthcare   Professional   Deliver   Specified   Specif												- Caused/Prolonged			
Recovering/Resolving - Caused/Prolonged Hospitalisation),  Urticaria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)  EU-EC- 10010871336  6/12/2021 Spontaneous Non Healthcare Professional Realthcare Realthcare Recovered/Resolved Resolved Resolved Resolved Resolved Resolving Committee Recovered Resolved Resolving Committee Recovered Resolving Recovered Resolving Committee Recovered Resolving Recovered Resolv															
EU-EC- 10010871345  BU-EC-												Recovering/Resolving - Caused/Prolonged			
Recovering/Resolving - Caused/Prolonged Hospitalisation),  Urticalisation),  Urticalisation),  EU-EC- 10010871336  O6/12/2021 Spontaneous Professional Profession															
EU-EC- 10010871345 Of 06/12/2021 Spontaneous Professional												Recovering/Resolving - Caused/Prolonged			
EU-EC- 10010871345 O6/12/2021 Spontaneous Recovering Resolving Professional Professional Professional Recovering Recovering Resolving Professional Relathcare Professional Relathcare Professional Relathcare Professional Relathcare Professional Relathcare Recovering Resolving Professional Recovering Recovering Resolving Professional Recovering Resolving Professional Recovering Resolving Professional Recovering Recovering Resolving Professional Recovering Recovering Recovering Resolving Professional Recovering Recovering Recovering Recovering Recovering Recovering Resolving Professional Recovering Re															
EU-EC- 10010871336 O6/12/2021 Spontaneous Healthcare Professional Professional D010871345 O6/12/2021 Spontaneous Healthcare Professi												(n/a - Recovering/Resolving			
10010871336   Healthcare Professional Realthcare Professional Realthcare Professional Realthcare Professional Realthcare Professional Realthcare Professional Realthcare Recovered/Resolved Resolved Re		EU-EC-	06/12/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Hospitalisation)	COMIRNATY [TOZINAMERAN]	[LEVOTHYROXINE SODIUM] (C	ICSR
EU-EC- 10010871345   Spontaneous   Healthcare Professional   Healthcare Professional   Healthcare Professional   Healthcare Professional   Not Professional   Specified   Specified   Specified   Not Abdominal pain upper (21d - Recovered/Resolved   COMIRNATY [TOZINAMERAN]   Not reported   ICSR   Specified			-, -2, 2021		Healthcare	Economic							(S - COVID-19 immunisation - Not applicable - [1d - n/a -	- Autoimmune thyroiditis - n/a	
Recovered/Resolved			06/12/2021	Spontaneous						Female	No		COMIRNATY [TOZINAMERAN]	Not reported	ICSR
https://dan.oma.gurana.gu/anglytico/sayy.dl/2Co							available	Icuis	Specificu				COVID-13 IIIIIIIIIIIIIIIII		

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				Economic Area						- Other Medically Important Condition),	Not applicable - [1d3mL - Intramuscular])		
										Back pain (21d - Recovered/Resolved - Other Medically Important Condition),			
										Chest pain (21d - Recovered/Resolved - Other Medically Important Condition),			
										Flank pain (24d - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (24d - Recovered/Resolved - Other Medically Important Condition),			
EU-EC-	06/12/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Palpitations (21d - Recovered/Resolved - Other Medically Important Condition) Arthralgia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010871358			Healthcare Professional	European Economic Area	available	Years	Specified			Unknown - Disabling, Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Chest pain (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Costochondritis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Joint swelling (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Pain (n/a - Unknown - Disabling, Other Medically Important Condition)			
EU-EC- 10010871611	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Axillary pain (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Chest pain (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Myocarditis (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Palpitations (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Pericarditis (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Tachycardia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically			
EU-EC-		Spontaneous		Non	Not	12-17		Female	No	Important Condition) Blood pressure	   COMIRNATY [TOZINAMERAN]		ICSR

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10010871700			Professional	European Economic Area	available	Years	Specified			increased (n/a - Unknown - ),	(S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])		
										Diarrhoea (n/a - Unknown - ), Erythema (n/a -			
										Unknown - ),			
										Feeling hot (n/a - Recovering/Resolving - ),			
										Pruritus (n/a - Unknown - ),			
										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010871758	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Discomfort (n/a - Unknown - ),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010871864	06/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	<u>ICSR</u>
										Chest pain (n/a - Unknown - Other Medically Important Condition),	,		
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Heart rate increased (n/a - Unknown - Other Medically Important Condition),			
										Red blood cells urine positive (n/a - Unknown - ),			
										Respiration abnormal (n/a - Unknown - Other Medically Important Condition),			
										Urinary sediment present (n/a - Unknown - ),			
EU EO	06/42/2024		Non	New	N	12.47	No.	I		White blood cells urine positive (n/a - Unknown - )	COMMONATA (TOTALAMEDANI	N. A	YCCD
EU-EC- 10010871875		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified		No	Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)		Not reported	ICSR
EU-EC- 10010872676		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010872759	06/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Blood pressure decreased (n/a - Unknown - Disabling),	n/a])		
										Chills (n/a - Recovering/Resolving - Disabling),			
										Dizziness (n/a - Unknown - Disabling),			
										Fatigue (n/a - Recovering/Resolving - Disabling),			
										Headache (n/a - Recovering/Resolving - Disabling),			
										Injection site reaction (n/a - Recovering/Resolving - Disabling),			
										Malaise (n/a - Recovering/Resolving - Disabling),			

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										Nausea (n/a - Recovering/Resolving - Disabling),			
										Pyrexia (n/a - Recovering/Resolving - Disabling), Sleep disorder (n/a -			
										Unknown - Disabling)			
EU-EC- 10010872955	06/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Menstruation irregular (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010873128	06/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oligomenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[DIPHTHERIA AND TETANUS VACCINE, DIPHTHERIA TOXOID, TETANUS TOXOID, ALGELDRATE, DIPHTHERIA TOXOID, TETANUS TOXOID, ALUMINIUM, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, ALGELDRATE] (C-n/a-n/a-[n/a-n/a],	ICSR
												[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]), [IBUPROFEN] (C -	
												Dysmenorrhoea - n/a - [n/a - n/a - Oral]),  [PARACETAMOL] (C - Pain -	
EU-EC-	06/12/2021	Spontaneous		European	Not	12-17	Adult	Female	No		COMIRNATY [TOZINAMERAN]	n/a - [n/a - n/a - Oral]) Not reported	ICSR
10010873159			Healthcare Professional	Economic Area	available	Years				Resolved - ), Intermenstrual	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										bleeding (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010873185	06/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Muscular weakness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nystagmus (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010873295		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10010856480	05/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Chills (3d - Recovered/Resolved - ),			
										Malaise (3d - Recovered/Resolved - ), Myalgia (3d -			
										Recovered/Resolved - ), Nausea (2d -			
										Recovered/Resolved - ),  Vomiting (3d -			
EU-EC-	05/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Recovered/Resolved - ) Amenorrhoea (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010857793			Healthcare	Economic Area	available	Years				Recovered/Resolved - ), Lymphadenopathy (n/a -	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Recovered/Resolved - )	 		
EU-EC- 10010857917	U5/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	remale	No	Circulatory collapse (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (0d - Recovered/Resolved			
										recovered/kesolved			

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											Limb discomfort (0d Recovered/Resolved			
	EU-EC- 10010857927	05/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition) Arthralgia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
	1001003/32/				Area	available	Icars				Resolved - ),  Cough (n/a - Not Recovered/Not	- n/a - n/a])		
											Resolved - ), Diarrhoea (n/a - Not Recovered/Not			
											Resolved - ), Headache (n/a - Not Recovered/Not			
											Resolved - ), Nausea (n/a - Not Recovered/Not			
											Resolved - ), Pain in extremity (n/a - Not Recovered/Not			
											Resolved - ),  Pyrexia (n/a - Not Recovered/Not Resolved - ),			
											Vomiting (n/a - Not Recovered/Not Resolved - )			
	EU-EC- 10010858062	05/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza (8d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
											Sinusitis (8d - Recovered/Resolved - )			
	EU-EC- 10010858661	05/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (28d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
											Obstructive airways disorder (28d - Recovering/Resolving - ),			
											Pulmonary function test decreased (28d - Recovering/Resolving - )			
	EU-EC- 10010859111	05/12/2021	Spontaneous		Economic	Not available		Adolescent	Male	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
											Injection site pain (1d - Recovered/Resolved			
	EU-EC- 10010860061	05/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epilepsy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
	EU-EC- 10010860219	05/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	<u>ICSR</u>
	EU-EC- 10010860248	05/12/2021	Spontaneous	Non Hea <b>l</b> thcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (5d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
											Sensory level abnormal (5d - Recovered/Resolved - ),			
											Visual impairment (5d - Recovered/Resolved			
	EU-EC- 10010860296	05/12/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	(C - Immunisation - n/a - [n/a	ICSR
				Professional	Area						Medically Important Condition),  Vaccination failure	- 2{DF} - n/a])	- 1{DF} - n/a])	
											(n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10010860495	05/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	- ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
											Fatigue (1d - Recovering/Resolving - ),			
											Pyrexia (1d - Recovering/Resolving - )			
	EU-EC- 10010860520	05/12/2021	Spontaneous			Not available	12-17 Years	Adolescent	Male	No	Erythema (1d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>

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										Pruritus (1d - Not Recovered/Not Resolved - ),			
										Rash (1d - Not Recovered/Not Resolved - ),			
										Skin discomfort (1d - Not Recovered/Not Resolved - )			
EU-EC- 10010860572	05/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Rash (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Varicella post vaccine (n/a - Recovering/Resolving -)			
EU-EC- 10010860592	05/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Influenza (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Rheumatoid arthritis (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010861169	05/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Cough (n/a - Not Recovered/Not Resolved - ),			
										Diarrhoea (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
	05/40/0004					10.15				Vomiting (n/a - Not Recovered/Not Resolved - )			1000
EU-EC- 10010862126	05/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Decreased appetite (5d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Dyspnoea (5d - Recovered/Resolved - ),			
										Ocular hyperaemia (5d - Recovered/Resolved - ),			
										Oedema (5d - Recovered/Resolved - ),			
										Pyrexia (5d - Recovered/Resolved - ),			
										Vomiting (5d - Recovered/Resolved - )			
EU-EC- 10010862462	05/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Not Recovered/Not Resolved - Other Medically Important	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	NOT CLASSIFIED [NOT AVAILABLE] (C - Dysmenorrhoea - n/a - [n/a - n/a - n/a]),	ICSR
										Condition),  Dizziness (n/a - Recovering/Resolving		[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]),	
										- Other Medically Important Condition),		[TOZINAMERAN] (C - n/a - n/a - [n/a - n/a - n/a])	
										Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pallor (n/a - Not Recovered/Not Resolved - Other Medically Important			

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										Condition),  Paraesthesia (1d - Recovered/Resolved - Other Medically Important Condition),  Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010851953	04/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (2d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving - ), Rash (n/a -			
EU-EC- 10010852269	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovering/Resolving - ) Disturbance in attention (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Fatigue (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10010852406	04/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- ) Epilepsy (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ETHOSUXIMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010852477	04/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	[DESOGESTREL] (C - Menstrual disorder - n/a - [n/a - 1{DF} - Oral])	ICSR
										Dyspnoea exertional (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010852592	04/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Respiratory fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10010852616	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blister (n/a - Not Recovered/Not Resolved - ), Burning sensation (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Hyperpyrexia (n/a - Not Recovered/Not Resolved - ), Pruritus (n/a - Not			
EU-EC-	04/12/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Recovered/Not Resolved - ) Bell's palsy (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
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10010852658			Healthcare Professional	Economic Area	available	Years	Specified			Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010852845	04/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC- 10010852890	04/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (38d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Amenorrhoea (38d - Recovered/Resolved - )			
EU-EC- 10010852973	04/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rhinitis allergic (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
10010853000		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		ICSR
EU-EC- 10010853126	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (4d - Recovered/Resolved - ), Headache (4d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Nausea (4d - Recovered/Resolved - )			
EU-EC- 10010853156	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010853163	04/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
EU EO	0.4.4.2./2021					10.17				Pyrexia (n/a - Not Recovered/Not Resolved - )			1000
EU-EC- 10010853226	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010853258	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010854170	04/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Malaise (1d - Recovered/Resolved -)			
EU-EC- 10010854286	04/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
EU EO	04/42/2024	Constant	New	F	Niet	12.17	Note	F	N	Myalgia (n/a - Not Recovered/Not Resolved - )	COMIDNATI/ FTOTINAMEDANI	Network	TOOD
EU-EC- 10010854306	04/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Recovering/Resolving - ),			
EU EC	04/12/2025	Cnort	Non	E.u	Not	12.17	Adel	For'	NI-	Syncope (n/a - Not Recovered/Not Resolved - )	COMIDNATY (TOTAL AND	Not vanouts -	ICCO
EU-EC- 10010854709	U4/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	гетаве	No	Arthralgia (1d - Recovered/Resolved - ),	(S - COVID-19 immunisation -	пос терогсеа	ICSR

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										Chills (n/a - Not Recovered/Not Resolved - ),	Not applicable - [n/a - 1{DF} - n/a])		
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Syncope (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010854940	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disturbance in attention (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - )			1000
EU-EC- 10010855329	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (1d - Recovered/Resolved -), Chills (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Resolved - ), Fatigue (2d -			
										Recovered/Resolved - ), Headache (0d -			
										Recovered/Resolved - ), Injection site			
										haematoma (2d - Recovered/Resolved -),			
										Malaise (n/a - Recovering/Resolving - ),			
										Myalgia (1d - Recovered/Resolved -),			
										Nausea (n/a - Recovering/Resolving - ),			
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10010855656		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Dyspnoea (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10010855668	04/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010855671	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Cough (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Dyspnoea (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Weight bearing difficulty (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010855675	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Vaccination site pain (1d - Recovered/Resolved			
EU-EC- 10010855684	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010855690	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
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										Caused/Prolonged Hospitalisation),			
										Syncope (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010855698	04/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal discomfort (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Haematochezia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010855711	04/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010855787	04/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Dizziness (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Tachycardia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010855792	04/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Extrasystoles (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Syncope (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010855806	04/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Not Recovered/Not Resolved - ), Influenza like illness	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
511.50	02/42/2024		N.	-		12.17				(0d - Not Recovered/Not Resolved - )	TTGTVNAMED AND (G., /		1000
EU-EC- 10010839654		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Asthenia (1d - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010839655		Spontaneous	Healthcare Professional			12-17 Years	Not Specified	Female	No	Asthenia (1d - Not Recovered/Not Resolved - )	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010839656	03/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - ), Chest pain (n/a -	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
										Unknown - ), Fatigue (n/a -			
										Unknown - ), Palpitations (n/a - Unknown - ),			
										Rhinorrhoea (n/a - Recovering/Resolving - )			
EU-EC- 10010839829	03/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10010840000	03/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010840239	03/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Hyperpyrexia (n/a - Not Recovered/Not Resolved - ),			
										Injection site pain (n/a - Not			

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:U-EC- .0010840243	03/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved - ), Hyperpyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	IC
										Not Recovered/Not Resolved - )			
J-EC- 1010840287	03/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	Ī
										Pyrexia (0d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition),			
										Vision blurred (0d - Recovered/Resolved - Other Medically Important Condition)			
J-EC- 010840291	03/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	1
										Supraventricular tachycardia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
010840300		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		-
010840768		Spontaneous	Healthcare Professional	Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
J-EC- 0010840800	03/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Extrasystoles (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Heart rate irregular (n/a - Unknown - Other Medically Important Condition),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pericarditis (n/a - Unknown - Other Medically Important Condition),			
										Suspected COVID-19 (n/a - Unknown - ),			
1.50	00//00	Curi	11	N	Mari	12:	l l			Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMPANY (T	No.	
J-EC- 1010840984	03/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(22d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
										Cough (22d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Diarrhoea (22d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
					1	1	1	1	1	Oropharyngeal	1		

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										discomfort (22d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Throat tightness (22d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010840988	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Headache (2d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
				Area						Neutropenia (7995min - Recovered/Resolved - Other Medically Important Condition),	Intramuscular])		
										Pyrexia (1d - Recovered/Resolved - ),			
										White blood cell count decreased (6d - Recovered/Resolved			
EU-EC- 10010840990	03/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Breast swelling (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Swelling (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010841056	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Blood pressure systolic increased (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				Area						Other Medically Important Condition),	Intramuscular])		
										Hypertension (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010841181	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Multisystem inflammatory syndrome in children (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010841619	03/12/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Eczema (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
			Professional	Economic Area						Condition),	Not applicable - [n/a - n/a - n/a])		
										Eye allergy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Hypersensitivity (n/a - Recovered/Resolved - Other Medically			
EU-EC- 10010841628	03/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Cough (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]),	Not reported	ICSR
										Lethargy (n/a - Recovered/Resolved - ),	[A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014,		
										Oropharyngeal pain (n/a - Recovered/Resolved -),	X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009		
										Pain in extremity (n/a - Recovered/Resolved -),	(H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN		
										Pyrexia (n/a - Recovered/Resolved - ),	(A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN		
 			utine te	4113C						Respiratory distress	(B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015		00/7
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											(H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Immunisation - Not applicable - [n/a - n/a - n/a]),  [HUMAN PAPILLOMAVIRUS VACCINE] (S - Immunisation - Not applicable - [n/a - n/a		
EU-EC- 10010841675	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No		n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010841685	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010841693	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition)  Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010841697	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010841706	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - ), Fatigue (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Infection (n/a - Not Recovered/Not Resolved - ),			
										Myopericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010841872	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010842040	03/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Troponin increased (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010842111	03/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	present (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Demyelination (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Diplopia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Dizziness (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition)			
EU-EC- 10010842364	03/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a -	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICSR
										Injection site pain (n/a - Recovering/Resolving - ),	MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Lymphadenopathy (n/a - Recovering/Resolving -),			
										Neck pain (n/a - Recovering/Resolving - ),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10010842378	03/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
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	ICSR	Not reported	TOZINAMERAN] (S - COVID- 19 immunisation - Not	/a - Not ecovered/Not esolved - Other edically Important	No	Male			European Economic	Healthcare	Spontaneous	03/12/2021	
Contraction	ICSR	Not reported	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	ecovering/Resolving Other Medically oportant	No	Male			European Economic	Healthcare	Spontaneous	03/12/2021	
Recoveragifical Recoveragifi				/a - Unknown - ther Medically nportant									
EU-EC   03/12/2021   Spontaneous   Non   Healthcare   European   Professional   Recovered/Not   Recovered/No				ecovered/Not esolved - Other edically Important									
ELFEC- 10010842847   Sportaneous   Non   Healthcare   European   Not   Specified   N				ecovered/Not esolved - Other edically Important									
Healthcare   Economic   Professional   Area   Area   Area   Area   Professional   Area   Area   Professional   Professional   Area   Professional   Professional   Area   Professional   Pr				ecovered/Not esolved - Other edically Important									
EU-EC- 10110844105  EU-EC- 10110844107  EU-EC- 10110844108  EU-EC-	ICSR	Not reported	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	nknown - ),	No	Male			Economic	Healthcare	Spontaneous	03/12/2021	
EU-EC- 10010844066 03/12/2021 Spontaneous Healthcare European Not Resistance of Healthcare European Not Resistance of Healthcare European Not Resistance (Natural Professional Area (Na				eadache (n/a -									
EU-EC- 100108441066 BU-EC-				/perhidrosis (n/a -									
EU-EC- 10010844066				nknown - ),									
Professional Economic Area  Professional Area  Professional Economic PlumAra Figure PlumAra Figure Professional Area  Professional Recovering/Resolving (5 - n/a - n/a - [n/a - n/a - n/a				nknown - Other edically Important									
EU-EC- 10010844186  EU-EC- 1001084478  EU-EC- 10010	NE] (C - n/a - g - Oral]), FORMOTEROL IYDRATE] (C - i- 2{DF} -	DESLORATADINE [DESLORATADINE] (C n/a - [n/a - 5mg - Oral [BUDESONIDE, FORMO FUMARATE DIHYDRATI n/a - n/a - [n/a - 2(DF Respiratory (inhalation	(S - n/a - n/a - [n/a - n/a - n/a])	ecovering/Resolving Caused/Prolonged	No	Male			Economic		Spontaneous	03/12/2021	
EU-EC- 10010844186    Spontaneous   Spontaneous   Spontaneous   Spontaneous   Healthcare   Professional   European   Healthcare   Professional   Spontaneous   Spontaneous	FUROATE E] (C - n/a - n/a - Nasal]),	[MOMETASONE FUROA MOMETASONE FUROA MONOHYDRATE] (C - r - [n/a - 200ug - Nasal]											
EU-EC- 10010844186	SODIUM] (C - - 5mg - Oral]),	MONTELUKAST SODIU n/a - n/a - [n/a - 5mg											
EU-EC- 10010844738		[TERBUTALINE SULFAT n/a - n/a - [n/a - n/a - Not reported	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	/a - Unknown - her Medically	No	Female			Economic	Healthcare	Spontaneous	03/12/2021	
EU-EC- 10010844738 O Spontaneous Non Healthcare Professional Healthcare Professional Non Healthcare Professional Healthcare Professional Non Not reported Not Non Not reported Not Non Not reported Not Not Patigue (0d - Recovered/Resolved - ), Headache (0d - No Not reported Not Professional Not reported Not Professional Not reported Not Patigue (0d - No Not Professional Not Patigue (0d - No Not Professional Not Pr				ndition), ncope (n/a -									
EU-EC- 10010844748    Spontaneous   Non Healthcare Professional   Heal	<u>ICSR</u>	Not reported	(S - Immunisation - n/a - [n/a	reatening) /spnoea (2d - ecovered/Resolved	No	Male	Adolescent		Economic	Healthcare	Spontaneous	03/12/2021	
Headache (0d -	<u>ICSR</u>	Not reported	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	ospitalisation) tigue (0d - ecovered/Resolved	No	Male	Adolescent		European Economic	Non Healthcare	Spontaneous	03/12/2021	
Recovered/Resolved - ),			n/a - n/a <u>]</u> )	eadache (0d - ecovered/Resolved					Area	Professional			
Injection site pain (Od - Recovered/Resolved				jection site pain d - ecovered/Resolved									
EU-EC- 03/12/2021 Spontaneous Healthcare Professional 10010844947 Spontaneous	ICSR	Not reported	(S - COVID-19 immunisation - Not applicable - [0d3mL -	notophobia (6d - ecovered/Resolved	No	Male	Adolescent		Economic		Spontaneous	03/12/2021	
Professional Area   Resolved - )   Not applicable - [n/a - 1{DF}		[SELENIUM SULFIDE]   - n/a - [n/a - n/a - n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	ot Recovered/Not	No	Male	Adolescent		Economic	Healthcare	Spontaneous	03/12/2021	
	(C - n/a - n/a -	[FLUTICASONE PROPIO SALMETEROL] (C - n/a [n/a - n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	rpura (n/a - Not ecovered/Not	No	Male	Adolescent		Economic	Healthcare	Spontaneous	03/12/2021	
EU-EC- 10010845997 03/12/2021 Spontaneous Healthcare Professional Professional Reconomic Area Professional Professional Reconomic Area Professional Reconomic Area Professional Reconomic Area Professional Reconomic Area Professional Reconomic Reconomic Area Professional Reconomic Reconomic Area Professional Reconomic Reconomic Area Professional Reconomic Reconomic Reconomic Area Professional Reconomic Re	<u>ICSR</u>	Not reported	COMIRNATY [TOZINAMERAN]	eadache (n/a - ecovered/Resolved	No	Male			Economic		Spontaneous	03/12/2021	

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										Important Condition),	Not applicable - [n/a - n/a - Intramuscular])		
										Pyrexia (n/a - Recovered/Resolved - ),			
										Vaccination site pain (n/a -			
EU-EC-	03/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Recovered/Resolved - ) Alanine	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010846063	03/12/2021	Sportaneous	Professional		available	Years	Specified	Male		aminotransferase increased (n/a - Unknown - ),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSK
										Blood glucose increased (n/a - Unknown - ),			
										Blood lactate dehydrogenase increased (n/a - Unknown - ),			
										Blood pressure decreased (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Cough (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Erythema (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Fibrin D dimer increased (n/a - Unknown - ),			
										Glucose urine present (n/a - Unknown - ),			
										Mean cell volume decreased (n/a - Unknown - ),			
										Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Rash (n/a - Unknown - Other Medically Important Condition),			
										Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Wheezing (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010846067	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperthyroidism (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC- 10010846125	03/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female		Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Cold sweat (n/a - Recovered/Resolved - ),			
										Feeling cold (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved - ),			
EU-EC-	03/12/2024	Spontaneous	Non	Furonosa	Not	12-17	Not	Female	No	Presyncope (n/a - Recovered/Resolved - ) Abdominal pain	COMIRNATY [TOZINAMERAN]	II EVOTHYDOVINIE	ICSR
10010846129	03/ 12/ 2021	- Σρυτιαπeous	Healthcare	European Economic Area	available	Years	Specified	i eniale	INU	upper (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Autoimmune thyroiditis - n/a - [n/a - n/a - Oral])	ICOK
										Blood pressure decreased (n/a - Unknown - Caused/Prolonged			

ı										Hospitalisation),			
										Blood pressure fluctuation (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Respiratory arrest (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Vaccination site pain			
EU-EC-	03/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Recovered/Resolved - ) Chest pain (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10010846143			Professional	European Economic Area	available	Years	Specified			Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a -	(S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])		
										Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010846148	03/12/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Alopecia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10010846153	03/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Unknown - Other		Not reported	ICS
										Injection site hypoaesthesia (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
										Lymphadenopathy (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Neuropathy peripheral (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010846162	03/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (6h - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Dyspnoea (6h - Recovered/Resolved - ),			
										Headache (6h - Recovered/Resolved -),			
										Myalgia (6h - Recovered/Resolved - ),			
										Oropharyngeal pain (6h - Recovered/Resolved			
										Throat tightness (6h			
EU-EC- 10010846184	03/12/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	- Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Hospitalisation),  Myocardial necrosis (n/a - Not			
tna://dan.a	ma euror	 pa.eu/anal	 vtics/saw.	 dll?Go						Recovered/Not			30/

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											Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
	EU-EC- 10010846209	03/12/2021	Spontaneous			Not available		Not Specified	Female	No	Hospitalisation) Abdominal pain (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - Gastrooesophageal reflux	ICSR
					Aled						Chills (n/a - Not Recovered/Not Resolved - Disabling),	ilyajj	disease - n/a - [n/a - n/a - n/a])	
											Decreased appetite (n/a - Not Recovered/Not Resolved - Disabling),			
											Fatigue (n/a - Not Recovered/Not Resolved - Disabling),			
											Headache (n/a - Not Recovered/Not Resolved - Disabling),			
											Myalgia (n/a - Not Recovered/Not Resolved - Disabling),			
											Nasopharyngitis (n/a - Not Recovered/Not Resolved - Disabling),			
											Nausea (n/a - Not Recovered/Not Resolved - Disabling)			
	EU-EC- 10010846226	03/12/2021	Spontaneous		Economic	Not available		Not Specified	Male	No	Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
											Epilepsy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Tongue biting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
	EU-EC- 10010846807	03/12/2021	Spontaneous	Healthcare		Not available		Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	<u>ICSR</u>
											Learning disorder (n/a - Not Recovered/Not Resolved - )	- n/a])		
	EU-EC- 10010846848	03/12/2021	Spontaneous			Not available	12-17 Years	Not Specified	Male	No	- Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	HYDROCHLORIDE] (C - Asthma, Bronchitis chronic - n/a - [n/a - n/a - n/a]),	ICSR
											Chronic cutaneous lupus erythematosus (n/a - Unknown - Other Medically Important		[ASCORBIC ACID, RIBOFLAVIN, DEXTRIN] (C - Carnitine deficiency, Dysphagia - n/a - [n/a - n/a - n/a]),	
											Condition),  Cutaneous vasculitis (n/a - Unknown - Other Medically Important Condition),		[BACILLUS SUBTILIS, LACTOMIN, BIFIDOBACTERIUM] (C - Chronic gastritis, Gastrooesophageal reflux disease - n/a - [n/a - n/a - n/a]),	
											Feeling hot (n/a - Unknown - ),		[CARBOCISTEINE] (C - Asthma, Bronchitis chronic - n/a - [n/a - n/a - n/a]),	
											Hypersensitivity vasculitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),		[DAIKENCHUTO, GINGER, GINSENG, ZANTHOXYLUM FRUIT, GINSENG] (C - Dyspepsia - n/a - [n/a - n/a - n/a]),	
											Pyrexia (6d - Recovered/Resolved - ), Rash (n/a - Recovering/Resolving		[DEXTRIN, FISH OIL, MINERALS NOS, VITAMINS NOS, AMINO ACIDS, MILK PROTEIN CONCENTRATE, RAPESEED OIL] (C - Carnitine	
											- ), Rash (n/a - Unknown		deficiency, Dysphagia - n/a - [n/a - n/a - n/a]),	

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										- ), Rash papular (n/a -		[GINSENG, RIKKUNSHITO] (C - Dyspepsia - n/a - [n/a - n/a - n/a]),	
										Unknown - ), Swelling (n/a - Unknown - )		[LANSOPRAZOLE] (C - Chronic gastritis, Gastrooesophageal reflux disease - n/a - [n/a - n/a - n/a]),	
												[LEVOCARNITINE] (C - Carnitine deficiency, Dysphagia - n/a - [n/a - n/a - n/a]),	
												[MOSAPRIDE, MOSAPRIDE CITRATE] (C - Chronic gastritis, Gastrooesophageal reflux disease - n/a - [n/a - n/a - n/a]),	
												[PRANLUKAST, PRANLUKAST HYDRATE] (C - Asthma, Bronchitis chronic - n/a - [n/a - n/a - n/a])	
U-EC- 0010847173	03/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		ICS
										Cardiac discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Hyperhidrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
U-EC- 0010847184	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Aspartate aminotransferase increased (n/a -		CELLCEPT [MYCOPHENOLATE MOFETIL] (C - Nephrotic syndrome - n/a - [n/a - n/a - Oral])	IC
										C-reactive protein increased (n/a - Unknown - ), Fibrin degradation			
										products increased (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolving - Other Medically			
U-EC- 0010847768	03/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Chest pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
				Alca						Myocarditis (110h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	Internascular Jy		
										Pyrexia (0d - Recovered/Resolved			
U-EC- 0010848003	03/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	(n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Altered state of consciousness (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling, Other Medically Important Condition),			
										Arrhythmia (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling, Other Medically Important Condition),			
										Cardiac arrest (n/a - Recovered/Resolved With Sequelae - Life			

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											Hospitalisation, Disabling, Other Medically Important Condition),			
											Dehydration (n/a - Recovered/Resolved With Sequelae - ),			
											Ejection fraction abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling),			
											Fall (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling),			
											Hepatic enzyme increased (n/a - Recovered/Resolved With Sequelae - ),			
											Hypoxic-ischaemic encephalopathy (n/a			
											Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
											Inflammation (n/a - Recovered/Resolved With Sequelae - ),			
											Left ventricular hypertrophy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling),			
											Portal venous gas (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
											Pyrexia (n/a - Recovered/Resolved With Sequelae - ),			
											Superior mesenteric artery syndrome (n/a			
											Recovered/Resolved With Sequelae - Other Medically Important Condition),			
											Ventricular fibrillation (n/a - Recovered/Resolved			
											With Sequelae - Life Threatening, Disabling, Other Medically Important Condition),			
											Vomiting (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)			
	U-EC- 0010848153	03/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Decreased appetite (4wk - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
											Nausea (4wk - Recovering/Resolving - )			
1	0010848231		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Seizure (n/a - Recovering/Resolving - Other Medically Important Condition)			<u>ICSR</u>
	U-EC- 0010848255	03/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
											Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Loss of consciousness (1d -			

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										Recovered/Resolved - Other Medically Important Condition),			
										Tetany (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010848342	03/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Immunisation reaction (n/a - Recovered/Resolved -)			
EU-EC- 10010848401	03/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Atypical pneumonia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Disease recurrence (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010848443		Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Adolescent		No	-)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		ICSR
EU-EC- 10010848444		Spontaneous	Healthcare Professional	European Economic Area	Not available	Years	Adolescent		No	Immunisation reaction (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		ICSR
EU-EC- 10010848482		Spontaneous	Professional	European Economic Area	Not available	Years	Adolescent		No	-)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		ICSR
EU-EC- 10010848504	03/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	remale	No	Influenza like illness (n/a - Recovering/Resolving - ), Nausea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	03/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Recovering/Resolving - ) Abdominal pain (1wk	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010848509	03,12,2021	Sportaneous		Economic Area	available	Years	radieseen	remale		Recovered/Resolved - ), Decreased appetite	(S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	That reported	1001
										(1wk - Recovered/Resolved - ),			
										Influenza like illness (1wk - Recovered/Resolved - )			
EU-EC- 10010848529	03/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Gastrointestinal disorder (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Influenza like illness (n/a - Recovering/Resolving -)			
EU-EC- 10010848553	03/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Influenza like illness (n/a - Not Recovered/Not Resolved - ),	,		
										Paraesthesia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010848585	03/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Influenza like illness (n/a - Recovered/Resolved -)	,		
EU-EC- 10010848607	03/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Influenza like illness (n/a - Not Recovered/Not Resolved - ),			
										Loss of consciousness (n/a - Recovered/Resolved - ),			
										Malaise (n/a -			

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										Recovered/Resolved - ),			
										Polymenorrhoea (n/a - Not Recovered/Not Resolved - ),			
										Vomiting (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010848711	03/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10010848759	03/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angioedema (24h - Recovered/Resolved - ), Urticaria (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC-	02/12/2021	Spontaneous	Lloalth gare	European	Not	12-17	Adolescent	Mala	No	Recovered/Resolved - ) Herpes zoster (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10010848767	03/12/2021	Sportaneous			available	Years	Adolescent	male		Not Recovered/Not	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	100
EU-EC- 10010849030	03/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
										Fatigue (n/a - Not Recovered/Not Resolved - ),	.,,,,,		
										Malaise (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
	02/42/2024	C	Non	-	No.	12.17	Net	Family		Pyrexia (n/a - Not Recovered/Not Resolved - )	COMPAND (FROM NAMED AND		100
EU-EC- 10010849474	03/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICS</u>
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010849837	03/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Flushing (n/a - Recovered/Resolved - ),			
										Hypersensitivity (n/a - Recovered/Resolved -),			
										Throat irritation (n/a			
	03/12/2021	Spontaneous		European	Not	12-17	Adolescent	Male	No	Recovered/Resolved - ) Myalgia (2d -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10010849970			Healthcare Professional	Economic Area	available	Years				Unknown - ), Pulmonary pain (2d - Unknown - )	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010850231	03/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Threatening,	TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICS
										Pollakiuria (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Thirst (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other			
										Medically Important Condition),			

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										Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),			
										Weight decreased (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important			
EU-EC- 10010850313	03/12/2021	Spontaneous			Not available	12-17 Years	Adolescent	Male		Condition) Injection site pain (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010850315	03/12/2021	Spontaneous			Not available	12-17 Years	Adolescent	Female		- ) Influenza like illness (0d - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (0d - Recovering/Resolving - ), Vaccination site pain (0d - Recovering/Resolving - )			
EU-EC- 10010850881	03/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Bradycardia (0d - Recovered/Resolved - Other Medically Important Condition),			
										Feeling abnormal (0d			
										Recovered/Resolved - Other Medically Important Condition),			
										Pallor (0d - Recovered/Resolved - Other Medically Important Condition),			
										Presyncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010851120	03/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (5min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Chest discomfort (n/a - Unknown - Other Medically Important Condition),			
										Chest pain (1250min - Recovered/Resolved - Other Medically Important			
										Condition),  Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Electrocardiogram ST-T segment depression (n/a - Unknown - Other Medically Important Condition),			
										Heart rate decreased (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010851398		Spontaneous	Professional	European Economic Area	Not available	Years	Adolescent			-)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])		ICSR
EU-EC- 10010825336	02/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Musculoskeletal pain (n/a - Recovered/Resolved With Sequelae - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved With Sequelae - ),			

										Vomiting (n/a - Recovered/Resolved With Sequelae - )			
EU-EC- 10010825474	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (3d - Recovered/Resolved - ), Nausea (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Vomiting (3d - Recovered/Resolved			
EU-EC- 10010825476	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vertigo (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10010825679	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Endocarditis (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Headache (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010825777	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pericardial effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010826157	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Hyperhidrosis (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
				Area						Pallor (n/a - Unknown - ),	Intramuscular])		
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010826161	02/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010826185	02/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ALPRAZOLAM] (C - Sedative therapy - n/a - [n/a - n/a - Oral])	ICSR

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											Other Medically Important Condition),			
											Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Haematemesis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
											Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Pulmonary sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition),			
											Septic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically			
	EU-EC- 10010826206	02/12/2021	Spontaneous		Non European Economic	Not available		Not Specified	Female	No	Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
					Area							Intramuscular])		
											Troponin abnormal (n/a - Not Recovered/Not Resolved - )			
	EU-EC- 10010826244	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
	EU-EC- 10010826249	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
											Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
											Musculoskeletal stiffness (n/a - Unknown - )			
	EU-EC- 10010826260	02/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
											Myocarditis (n/a - Unknown - Other Medically Important Condition),			
											Palpitations (3d - Recovered/Resolved - )			
	EU-EC- 10010826552	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Chest pain (14h - Recovered/Resolved - )			
	EU-EC- 10010826565	02/12/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Headache (1h - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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				Economic Area						Syncope (1h - Recovered/Resolved - Other Medically Important Condition)	Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10010826572	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (50min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010826574	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSI
EU-EC- 10010826607	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bradycardia (n/a -		Not reported	ICS
EU-EC- 10010826620	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010826672	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (41min - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010826763	02/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Dysmenorrhoea - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - Influenza immunisation - n/a - [1d - 1{DF} - n/a])	ICS
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010827097	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Gait disturbance (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
										Muscular weakness (n/a - Unknown - Other Medically Important Condition),			
										Myalgia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010827117	02/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[OXYBUTYNIN HYDROCHLORIDE] (C - Bladder dysfunction - n/a - [n/a - n/a - Oral]),	ICS
										Chest pain (28d - Recovered/Resolved - Other Medically Important Condition),		[SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - Urinary tract infection - n/a - [n/a - n/a - Oral])	
										Cyanosis (21d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Fatigue (28d - Recovered/Resolved - Disabling), Heart rate increased			
										(28d - Recovered/Resolved - Other Medically Important Condition),			
										Hypothermia (n/a - Recovering/Resolving			

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										- Caused/Prolonged Hospitalisation),			
										Oxygen saturation decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain in extremity (171h -			
										Recovered/Resolved			
										Palpitations (21d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (3h - Recovered/Resolved - )			
EU-EC- 10010827132	02/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010827136	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Flushing (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010827144	02/12/2021	Spontaneous		Non European Economic Area	Not available		Not Specified	Male	No	Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition),			
										Orthostatic hypotension (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010827155	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Palpitations (n/a - Recovered/Resolved - ), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010827163	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic shock (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010827170	02/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Nephritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
EU 53	024275				N.	42.1-				Weight decreased (n/a - Unknown - Other Medically Important Condition)	COMPANY (FEG. 1997)	<u></u>	Tee:
10010827795		Spontaneous	Professional	Economic Area	Not available	Years	Not Specified	Male		Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		ICSR
EU-EC- 10010827813	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Pericarditis (n/a -			
										Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010827844	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (70min - Recovered/Resolved - ), Hyperhidrosis (70min - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	02/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Syncope (70min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010827945			Professional	Economic Area	available	Years				Recovered/Not Resolved - )	(S - n/a - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10010828617	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010828627	02/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Myalgia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Productive cough (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),			
										Sinus congestion (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Sinus headache (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)			
EU-EC- 10010828630	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Psychomotor hyperactivity (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	MELATONIN [MELATONIN] (C - Poor quality sleep - n/a - [n/a - n/a - n/a]),  [LISDEXAMFETAMINE DIMESYLATE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010828638	02/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010828655	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Lymphoma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	··· = 1)		
										Pain (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010828666	02/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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				Area						Medically Important Condition)	n/a])		
J-EC- ( 0010828706	02/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
J-EC- (0010828762	02/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Pericarditis (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
	02/12/2021	Spontaneous		Non	Not	12-17	Not	Female	No	Tachycardia (n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a -	TOZINAMERAN	Not reported	ICS
0010828814			Healthcare Professional	European Economic Area	available	Years	Specified			- Other Medically Important Condition),	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
J-EC- (	02/12/2021	Spontaneous	Non	Non	Not	12-17	Not	Mala	No	Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIDNATY FTO THAMED AND	Net reported	ICC
0010828836	02/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	Years	Specified	Male	No	Parkinsonism (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a])	Not reported	ICS
J-EC- 0010828847	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Pyrexia (2d - Recovered/Resolved - ), Vaccination site pain (36h -			
J-EC- 0010828869	02/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved - ) Chills (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICS
			Professional	Area			·			Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ),	Not applicable - [1d - n/a - n/a])		
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
J-EC- 0010828895	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (0d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
J-EC- 0010828932	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Face oedema (5d - Recovered/Resolved - ), Skin disorder (5d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
			Protessional	Area						Skin disorder (5d -			

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										-)			_
:U-EC- .0010828945	02/12/2021	Spontaneous	Professional		Not available	12-17 Years	Not Specified	Male	No	Hypersensitivity (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		IC
										Throat irritation (n/a - Unknown - Other Medically Important Condition)			
J-EC- 0010828992	02/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	10
J-EC- 0010829096	02/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	Ī
										Angina pectoris (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Hepatic enzyme increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Hyperhidrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
U-EC- 0010829101	02/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Malnutrition (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
U-EC- 0010830104	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	]
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
	02/12/2021	Spontaneous	Healthcare		Not	12-17	Not	Male	No	Arrhythmia (9d -	COMIRNATY [TOZINAMERAN]	Not reported	<u>I</u>

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10010830394			Professional	Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Palpitations (9d - Recovered/Resolved - Other Medically Important Condition),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010830801	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010831026	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICSR
										Feeling abnormal (n/a - Unknown - ),			
										Feeling hot (n/a - Unknown - ),			
										Lip erythema (n/a - Recovering/Resolving - ),			
										Lip pain (n/a - Not Recovered/Not Resolved - ),			
										Lip pain (n/a - Recovering/Resolving - ),			
										Lip swelling (n/a - Recovering/Resolving - )			
EU-EC- 10010831044	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea exertional (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Myalgia intercostal (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Painful respiration (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010831517	02/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010831555	02/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting projectile (n/a - Recovering/Resolving - Other Medically			
EU-EC- 10010831737	02/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Chest pain (28d - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	ICSR
				Area						Important Condition),	applicable - [1d - n/a - n/a])		

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										Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Maximal voluntary ventilation (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Myositis (n/a - Unknown - Other Medically Important Condition),			
										Nasopharyngitis (n/a			
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010831787	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										-),			
										Vulval ulceration (n/a - Recovered/Resolved			
EU-EC-	02/12/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	- Disabling)  Conjunctivitis (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010831869			Professional	Economic Area	available	Years	Specified			Unknown - Caused/Prolonged Hospitalisation)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010831874	02/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Somnolence (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Stridor (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010832170	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010832171	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		ICSR
EU-EC- 10010832195	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown - ), Skin abrasion (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010832198	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010832204	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				Area						Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),	Intramuscular])		
										Vomiting (n/a - Recovered/Resolved - )			
EU-EC- 10010832217	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotension (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010832251	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010832268	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eye movement disorder (n/a - Recovered/Resolved - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

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										Loss of consciousness (n/a - Recovered/Resolved - Life Threatening),			
										Pallor (n/a - Unknown - ),			
										Seizure (n/a - Recovered/Resolved - Life Threatening)			
EU-EC- 10010832332	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10010832367	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (81h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Headache (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (9h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010832378	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10010832379	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (28min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Vomiting (28min - Recovered/Resolved - )			
EU-EC- 10010832390	02/12/2021	Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSI
				Area						Dizziness (n/a - Recovered/Resolved - ),	Intramuscular])		
										Headache (n/a - Recovered/Resolved - ),			
										Peripheral coldness (n/a - Unknown - ),			
										Presyncope (38min - Recovered/Resolved - Other Medically Important Condition),			
										Pulse abnormal (n/a - Recovered/Resolved			
EU-EC-	02/12/2021	Spontaneous		European	Not	12-17	Not	Female	No	- ) Myocarditis (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010832470			Professional	Area	available	Years	Specified			Not Recovered/Not Resolved - Other Medically Important Condition)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10010832558	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Monoparesis (13d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10010832765	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eczema (n/a - Recovering/Resolving - Disabling), Skin disorder (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
										Recovering/Resolving - Disabling)			
EU-EC- 10010832834	02/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pruritus (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010832836	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Fatigue (n/a -   Recovered/Resolved  - ),			

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										Headache (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			
										Pain in extremity (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovered/Resolved - ),			
										Vomiting (0d - Recovered/Resolved - )			
EU-EC- 10010832841	02/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Unknown - ), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Unknown - ), Somnolence (2d - Recovered/Resolved	,		
										- ), Vaccination site swelling (5d -			
EU-EC- 10010833046	02/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved - ) Parosmia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
EU-EC-	02/12/2021	Spontaneous	Non	Area European	Not	12-17	Not	Male	No	Back pain (n/a -	Not applicable - [1d - n/a - Intramuscular]) TOZINAMERAN	Not reported	ICSR
10010833067			Healthcare Professional	Economic Area	available	Years	Specified			Pain (n/a - Unknown - ),	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])		
										Sensitive skin (n/a - Unknown - ),			
EU-EC- 10010833081	02/12/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Skin irritation (n/a - Unknown - ) COVID-19 immunisation (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSR
			Professional	Area						Unknown - ), Intermenstrual bleeding (n/a - Unknown - )	Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX- 024414)] (S - n/a - n/a - [n/a		
EU-EC- 10010833111	02/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Unknown - )	- n/a - Intramuscular])  COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010833187	02/12/2021	Spontaneous	Non Healthcare	European	Not available	12-17 Years	Child	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Pain in extremity (n/a - Not Recovered/Not Resolved - ),			
										Vaccination site movement impairment (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010833201	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Asthenia (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-	02/12/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Epistaxis (n/a - Unknown - ) Abdominal pain (n/a	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010833302			Healthcare Professional	Economic Area	available	Years	Specified			- Not Recovered/Not Resolved - )	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	,	
EU-EC- 10010833324	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010833704	02/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Wound (n/a - Recovering/Resolving - )			
EU-EC- 10010833878	02/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood glucose increased (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INSULIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10010833974	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Bradycardia (n/a -			

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										Recovered/Resolved - Other Medically Important Condition),			
										Depressed level of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Heart rate decreased (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - ),			
										Presyncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010833983	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Recovering/Resolving - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	ICSR
										Neck pain (n/a - Recovering/Resolving - )	applicable - [1d - n/a - Intramuscular])		
EU-EC- 10010834041	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010834100	02/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important Condition),			
										Pericarditis (n/a - Unknown - Other Medically Important Condition),			
										Tachycardia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010834297	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Eczema (n/a - Unknown - ),			
										Pruritus (n/a - Unknown - ), Pyrexia (n/a -			
EU-EC-	02/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Recovered/Resolved - ) Bradycardia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010834303			Professional	Economic Area	available	Years	Specified			- Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10010834311	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (30min - Recovered/Resolved -), Decreased appetite	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Unknown - ), Hypotension (30min			
										Recovered/Resolved			
										Syncope (30min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010834357	02/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Arthralgia (1d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Chills (1d - Recovered/Resolved - Disabling),			
										Fatigue (1d - Recovered/Resolved - Disabling),			

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										Feeling cold (1d - Recovered/Resolved - Disabling),			
										Headache (1d - Recovered/Resolved - Disabling),			
										Myalgia (1d - Recovered/Resolved - Disabling),			
										Pyrexia (1d - Recovered/Resolved - Disabling)			
EU-EC- 10010834387	02/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010834573	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Dysstasia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Headache (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Neuralgia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Neuritis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Viral infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010834598	02/12/2021	Spontaneous			Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Cough (n/a - Recovering/Resolving - ),			
										Nasopharyngitis (n/a - Recovered/Resolved -)			
EU-EC- 10010834602	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Gait disturbance (n/a	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Genital ulceration (n/a - Recovered/Resolved - Other Medically			
EU-EC- 10010834945	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Haemophagocytic lymphohistiocytosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			

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										Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10010834950	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angioedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Cough (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Dysphonia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Eye pruritus (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Hyperaemia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Inappropriate schedule of product administration (n/a - Unknown - ),			
										Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Paresis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Rash (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010835185	02/12/2021	Spontaneous		European Economic Area		12-17 Years	Adolescent	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010835222	02/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (0d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Hyperaesthesia (0d - Not Recovered/Not Resolved - ),			
										Malaise (0d - Not Recovered/Not Resolved - )			
EU-EC- 10010835225	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pulmonary pain (n/a - Recovered/Resolved			
EU-EC- 10010835238	02/12/2021	Spontaneous		European	Not	12-17	Adolescent	Female	No	- ) Injection site pain	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010635236			Healthcare Professional	Economic Area	available	Years				(0d - Recovered/Resolved - ),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Menstruation delayed (0d - Recovered/Resolved -)			
EU-EC- 10010835398		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 2{DF} - Intramuscular])		ICSR
EU-EC- 10010835405	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010835506	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010835513	02/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Child	Female	No	Chest pain (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

EU-EC-	02/12/2021	Cnonto	Non	European	Not	12.17	Adolescent	Eomal-	No	Recovered/Resolved -) Chest pain (n/a -	COMIDNATY ITOZIALANAEDANI	DELVAD ELLIDTA 104	I
10010835550		Spontaneous	Healthcare Professional	Economic	available	12-17 Years			INO	Chest pain (n/a - Recovered/Resolved - ), Influenza like illness (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	RELVAR ELLIPIA 184 MICROGRAMS/22 MICROGRAMS [FLUTICASONE FUROATE, VILANTEROL] (C- n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10010835556	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Disease recurrence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	<u>I</u>
										Endometriosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaginal haemorrhage			
711.50	02/12/2021	Constitution	Line like annua	5	Net	12.17			N	(n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMPNATY FTOTMAMERANI	National	
10010835760		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	'	Ī
EU-EC- 10010835791	02/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>I</u>
EU-EC- 10010835799	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Gastrointestinal disorder (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	Ī
EU-EC- 10010835801	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Gastrointestinal disorder (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	]
EU-EC- 10010835805	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cardiac arrest (1d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	
EU-EC- L0010835837	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovered/Resolved - ), Vertigo (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	
EU-EC- 1.0010836060	02/12/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Male	No	Disturbance in attention (n/a - Not Recovered/Not Resolved - ),  Fatigue (n/a - Not Recovered/Not Resolved - ),  Headache (n/a - Recovering/Resolving - ),  Injection site pain (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	
										Recovered/Not Resolved - ), Myalgia (n/a - Recovering/Resolving			
EU-EC- 1.0010836260	02/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovering/Resolving - ), Inappropriate schedule of product administration (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	
:U-EC- .0010836800	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	
EU-EC- 10010836804	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Abdominal pain (54h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cough (81h -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	
										Recovered/Resolved - ), Diarrhoea (3h - Recovered/Resolved			

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											Pyrexia (85h - Recovered/Resolved - ),			
											Vomiting (30min - Recovered/Resolved			
	EU-EC- 10010836808	02/12/2021	Spontaneous			Not available		Not Specified	Female	No	- ) Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Horbitalisation, Other Medically Important Condition),			
											Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Horbitalisation, Other Medically Important Condition),			
											Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Horpitalisation, Other Medically Important Condition),			
											Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
	EU-EC-	02/12/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not separted	ICSR
	10010837152	52, 12, 2021	Sportaneous		Economic	available		Specified	. Gnafe	110	Recovered/Not Resolved - ), Limb mass (n/a - Not Recovered/Not Resolved - ),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	посторогом	<u>acun</u>
											Thrombosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
	EU-EC- 10010837218	02/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available		Not Specified	Male		Aphthous ulcer (10d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
											Condition aggravated (n/a - Recovered/Resolved - Other Medically			
											Important Condition), Dizziness (0d - Recovered/Resolved			
											- ), Ear pain (n/a - Not			
											Recovered/Not Resolved - Other Medically Important Condition),			

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										Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product			
										administration (n/a - Unknown - ),			
										Oropharyngeal pain (3d - Recovered/Resolved			
:U-EC- 0010837324	02/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Aspartate aminotransferase increased (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	IC
										Blood creatine phosphokinase increased (n/a - Unknown - Other Medically Important Condition),			
										Blood lactate dehydrogenase increased (n/a - Unknown - ),			
										Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Feeling hot (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Gamma- glutamyltransferase decreased (n/a - Unknown - ),			
										Heart rate decreased (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Presyncope (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - )			
J-EC- 0010837378	02/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	Not applicable - [1d - n/a -	[INFLUENZA VIRUS] (C - Immunisation - n/a - [1d - n/a - n/a])	10
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rhinorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
J-EC- 0010837934	02/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	IC
										Heart rate increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Hemiplegia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Seizure (18735min - Recovered/Resolved - Caused/Prolonged Hospitalisation,			

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										Condition), Tic (18735min - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010838351	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
										- ), Pyrexia (n/a - Recovering/Resolving - ), Vaccination site pain			
										(n/a - Recovering/Resolving - )			
EU-EC- 10010838409	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site induration (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010838444	02/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010838453	02/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
										Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not			
										Recovered/Not Resolved - ), Pain in extremity			
										(n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not			
										Recovered/Not Resolved - )			
EU-EC- 10010838455	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menarche (5d - Recovered/Resolved - ), Menstruation	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	02/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	irregular (n/a - Unknown - ) Pruritus (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010838463	3-7-1-7-1-1	oponianios ao			available	Years				Recovering/Resolving - ), Skin reaction (n/a -	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a - More in ICSR])		
EU-EC-	02/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Recovering/Resolving - ) Lymphadenopathy	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010838467	32, 12, 2321	oponicaniosas	Healthcare Professional	Economic	available	Years	, and cooking	, emaic		(4d - Recovered/Resolved - ),	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	net reported	10011
										Vaccination site pain (4d - Recovered/Resolved -)			
EU-EC- 10010838489	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010838521	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Decreased appetite (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
										Early satiety (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010838557	02/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010838567	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Mastitis (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010838576		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010838739	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved - ), Pain in extremity	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										(1wk - Recovered/Resolved - ),			
										Somnolence (2d - Recovered/Resolved - ),			
										Vaccination site pain			

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										(1wk - Recovered/Resolved - ),			
										Vaccination site swelling (5d - Recovered/Resolved - )			
EU-EC- 10010838790	02/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
										Headache (0d - Recovered/Resolved -),	- n/a])		
										Injection site pain (n/a - Recovering/Resolving			
										- ), Malaise (n/a - Recovering/Resolving			
										- ), Myalgia (0d - Recovered/Resolved			
										- ),  Pyrexia (n/a - Recovering/Resolving			
EU-EC- 10010838843	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	- ) Hypersensitivity (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation	Not reported	ICSR
EU-EC- 10010838858	02/12/2021	Spontaneous	Non Healthcare	Area  European  Economic	Not available	12-17 Years	Adult	Female	No		Not applicable - [n/a - 1{DF} - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
			Professional	Area						Resolved - ), Heavy menstrual bleeding (n/a - Not	Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10010838974	02/12/2021	Spontaneous		European	Not	12-17 Years	Adolescent	Female	No	Recovered/Not Resolved - ) Discomfort (n/a -		[ADAPALENE] (C - Acne - n/a -	ICSR
10010838974			Professional	Economic Area	available	Years				Unknown - Disabling), Dizziness (1d -	(S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a]),	[[r/a - 1{DF} - Cutaneous])	
										Recovered/Resolved - Disabling), Dizziness (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
										Recovered/Not Resolved - Disabling),			
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling),			
										Gait disturbance (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC- 10010838992	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10010839061	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthma (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Cough (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010839111	02/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oropharyngeal pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	FUROATE] (C - Rhinitis allergic - n/a - [n/a - n/a - Nasal]),	<u>ICSR</u>
												OPATANOL [OLOPATADINE, OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]),	
												[BIFONAZOLE, CLOTRIMAZOLE] (C - Fungal infection - n/a - [n/a - n/a - Cutaneous]),	
												[CLOBETASOL PROPIONATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]),	
												[DERMATOPHAGOIDES PTERONYSSINUS] (C - Allergy prophylaxis - n/a - [n/a - n/a - Subcutaneous]),	
												[DESOGESTREL] (C - n/a - n/a - [n/a - n/a - Oral]),	
												[FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - n/a - Oral]),	
												[IBUPROFEN] (C - Pain - n/a - [n/a - n/a - Oral]),	
												[KETOCONAZOLE, KETOCONAZOLE PH. EUR.] (C -	

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												n/a - n/a - [n/a - n/a - Cutaneous]),	
												[PHLEUM PRATENSE (225)] (C - Allergy prophylaxis - n/a - [n/a - n/a - Subcutaneous]),	
												[PHLEUM PRATENSE (225)] (C - n/a - n/a - [n/a - n/a - Subcutaneous]),	
												[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])	
EU-EC- 10010839120	02/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	BETMIGA [MIRABEGRON] (C - Incontinence - n/a - [n/a - n/a - Oral]),	
												[DESMOPRESSIN, DESMOPRESSIN ACETATE, DESMOPRESSIN ACETATE TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
												[SOLIFENACIN, SOLIFENACIN SUCCINATE] (C - Hypertonic bladder - n/a - [n/a - n/a - Oral]),	
												[SOLIFENACIN, SOLIFENACIN SUCCINATE] (C - Incontinence - n/a - [n/a - n/a - Oral])	1
EU-EC- 10010839218	02/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tinnitus (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>I0</u>
EU-EC- 10010839225	02/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	10
										Dizziness (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010839327	02/12/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown - ),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	10
				Area						Anaphylactic shock (n/a - Unknown - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
										Dysmenorrhoea (n/a - Unknown - ),			
										Headache (n/a - Unknown - ),			
										Heavy menstrual bleeding (n/a - Unknown - ),			
										Vomiting (n/a - Unknown - )			
EU-EC- 10010811217	01/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- ), Vertigo (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	I
EU-EC-	01/12/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Recovering/Resolving - )  Lymphadenopathy	COMIRNATY [TOZINAMERAN]	Not reported	1
.0010811721	,,		Healthcare	Economic Area	available	Years	Specified			(n/a -	(S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])		-
EU-EC-	01/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Recovered/Resolved - )  Dizziness (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	10
0010812542	01/12/2021	Spontaneous		European Economic Area	available	Years	Specified	remale	INO	Unknown - ),  Dry mouth (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	1
				7 11 00						Unknown - ),  Nausea (n/a - Unknown - ),	and an account of		
										Syncope (n/a - Unknown - Other Medically Important Condition)			
U-EC- 0010812543	01/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	]
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vertigo (n/a -			

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										Vision blurred (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010812553	01/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Myalgia (n/a - Recovering/Resolving - ),			
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010812579	01/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Abdominal pain (n/a - Recovering/Resolving			
										- Other Medically Important Condition),			
										Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Erythema (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Feeling hot (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Rash (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Throat tightness (n/a - Recovering/Resolving - Other Medically			
										Important Condition), Urticaria (n/a -			
										Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010812598	01/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature abnormal (n/a - Unknown - ), Nausea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Unknown - ),  Vomiting (n/a -			
EU-EC- 10010812632	01/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Unknown - ) Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
EU-EC- 10010812652	01/12/2021	Spontaneous		Area Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Syncope (n/a - Recovered/Resolved	n/a])  (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10010812655	01/12/2021	Spontaneous		Area Non European	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Chest pain (n/a - Not Recovered/Not	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
				Economic Area						Resolved - ),  Dyspnoea (n/a - Not Recovered/Not Resolved - ),	Not applicable - [1d - n/a - n/a])		
										Lethargy (n/a - Not Recovered/Not Resolved - ),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other			

U-EC-	01/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Condition) Ataxia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	1
0010812659			Professional	European Economic Area	available	Years	Specified			- Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation),  Dizziness (n/a - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation),			
										Eye movement disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Gait disturbance (n/a Recovering/Resolving			
										- Caused/Prolonged Hospitalisation), Miller Fisher			
										syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Muscular weakness (n/a - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation), Neutrophil count			
										decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Presyncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Protein total increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
J-EC- 0010812672	01/12/2021	Spontaneous	Professional	Non European Economic Area	Not available		Not Specified	Male	No	Dyspnoea (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
				Aica						Electrocardiogram abnormal (n/a - Recovering/Resolving - ),	1,741)		
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pleuritic pain (n/a - Recovering/Resolving - )			
J-EC- 010812704	01/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Blood creatinine increased (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	_
				Area						Chest pain (n/a - Unknown - ),	n/a])		
										Electrocardiogram abnormal (n/a - Unknown - ),			
										Pericarditis (n/a - Unknown - Other Medically Important Condition),			
I EC	01/12/2021	Chantanaous	Haaltheara	Non	Not	12 17	Not	Malo	No	Troponin increased (n/a - Unknown - )	COMIDNATY [TOZINAMEDAN]	Not reported	_
J-EC- 0010812717	01/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bundle branch block right (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	nocreported	
										Chest pain (n/a - Not Recovered/Not Resolved - ),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - ),			
		I	I	I		1	I		1	Pericarditis (n/a -			

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EU-EC-	01/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10010813528	01,12,2021	эропшисоцэ	Professional	European Economic	available	Years	Specified	remale		- Unknown - ),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	not reported	1001
				Area						Chest pain (n/a - Unknown - ),	n/a])		
										Diarrhoea (n/a - Unknown - ),			
										Haematochezia (n/a - Unknown - Other Medically Important Condition),			
										Headache (n/a - Unknown - ),			
										Lethargy (n/a - Unknown - ),			
										Pyrexia (n/a - Unknown - )			
EU-EC- 10010813575	01/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved - ),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010813583	01/12/2021	Spontaneous	Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	i	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
				Area						Chest pain (n/a - Not Recovered/Not Resolved - ),	n/a])		
										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Troponin increased (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010813593	01/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Confusional state (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
				Area						Seizure (n/a - Unknown - Other Medically Important	Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010813609	01/12/2021	Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Condition)  COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Infection (n/a - Unknown - ),			
										Oropharyngeal pain (n/a - Unknown - )			
EU-EC- 10010813651	01/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site pain (n/a - Recovered/Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICSR
										Pyrexia (n/a - Recovered/Resolved - ),	MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])		
										Rash (.5d - Recovered/Resolved			
EU-EC- 10010813823	01/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	INTUNIV [GUANFACINE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - Oral]),	ICSR
										Enterocolitis haemorrhagic (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		[METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - Oral])	
										Haematochezia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-		Spontaneous		Non	Not	12-17	Not				COMIRNATY [TOZINAMERAN]	<del></del>	ICSR

				Economic Area						Medically Important Condition)	Not applicable - [1d - n/a -		
EU-EC- 10010813861	01/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysstasia (n/a - Unknown - ), Fall (n/a - Unknown - Other Medically	n/a])   COMIRNATY [TOZINAMERAN]   (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Important Condition), Grip strength decreased (n/a - Unknown - ),			
										Hot flush (n/a - Unknown - )			
EU-EC- 10010814196	01/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bronchitis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Nasal congestion (n/a - Unknown - ), Pyrexia (n/a -			
										Unknown - ), Tachycardia (1d -			
U-EC-	01/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Recovered/Resolved - ) Chest pain (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	IC
0010814225		,	Professional	European Economic Area	available	Years	Specified			Recovered/Resolved - ), Palpitations (n/a -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	·	
										Recovered/Resolved - ),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
:U-EC- .0010814238	01/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Atypical pneumonia (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	IC
										Body temperature increased (4d - Recovered/Resolved - Other Medically Important Condition),			
										Bronchospasm (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Condition aggravated (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Heart rate increased (1d - Recovered/Resolved - Other Medically Important Condition),			
										Myalgia (n/a - Unknown - ),			
										Oxygen saturation decreased (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- .0010814239	01/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	IC
				Area						- ),  Appendicitis (n/a - Recovering/Resolving - Other Medically	n/a])		
U-EC- 0010814317	01/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Balance disorder (n/a	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
										Dizziness (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010814399	01/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (20d - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
										Dyspnoea (20d - Not Recovered/Not Resolved - ),			

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										Influenza (20d - Not Recovered/Not Resolved - ),			
										Myalgia (20d - Not Recovered/Not Resolved - ),			
										Nausea (20d - Not Recovered/Not Resolved - )			
EU-EC- 10010814701	01/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female		Hypomenorrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10010814746	01/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea (n/a - Not Recovered/Not Resolved - ),			
										Malaise (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010815013	01/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immune thrombocytopenia (18d - Recovering/Resolving	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR	Not reported	ICSR
										- Other Medically Important Condition),	INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a3mL - Intramuscular])		
										Petechiae (18d - Recovering/Resolving - ),			
										Vaccination site pain (18d - Recovered/Resolved - )			
EU-EC- 10010815278	01/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female		Dyskinesia (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
				Area						Joint lock (n/a - Not Recovered/Not Resolved - ),	1,01)		
										Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010815284	01/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Vomiting (n/a - Recovered/Resolved - )			
EU-EC- 10010815341	01/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Sensitive skin (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010815415	01/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Circulatory collapse (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (n/a - Unknown - Other Medically Important Condition),			
										Loss of consciousness (1d - Recovered/Resolved			

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										- Other Medically Important Condition),			
										Nausea (1d - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Syncope (n/a - Unknown - Other Medically Important Condition),			
										Tinnitus (1d - Recovered/Resolved - Other Medically Important Condition),			
										Upper limb fracture (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010815454		Spontaneous	Professional	Non European Economic Area	Not available	Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	·	ICSR
EU-EC- 10010815545	01/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain lower (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Melaena (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10010815576		Spontaneous Spontaneous	Healthcare Professional	Area	Not available Not	Years	Not Specified	Female	No No	Tremor (n/a - Not Recovered/Not Resolved - ) Fatigue (5d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular]) COMIRNATY [TOZINAMERAN]		ICSR ICSR
10010815580	01/12/2021	Sportaneous	Healthcare Professional		available	Years	Not Specified	Female	INO	Recovered/Resolved - ), Headache (5d - Recovered/Resolved	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSK
										- ), Malaise (5d - Recovered/Resolved - ),			
										Nausea (5d - Recovered/Resolved - )			
EU-EC- 10010815751	01/12/2021	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (0d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Diarrhoea (4wk - Recovered/Resolved - ),			
										Dizziness (4wk - Recovered/Resolved - ),			
										Dyspnoea (4wk - Recovered/Resolved - ),			
										Fatigue (n/a - Recovered/Resolved - ),			
										Gastroenteritis viral (n/a - Recovered/Resolved - ),			
										Malaise (4wk - Recovered/Resolved - ),			
										Nausea (4wk - Recovered/Resolved -),			
EU-EC-	01/12/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Vomiting (4wk - Recovered/Resolved - ) Amenorrhoea (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010815916		·	Professional	Economic Area	available	Years	Specified			Not Recovered/Not Resolved - )	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC- 10010816557	01/12/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Bronchospasm (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>

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				Area						- Other Medically Important Condition),	n/a - [n/a - n/a - Intramuscular])		
										Rash (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010816682		Spontaneous			Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - ),	7-17		
										Muscle spasms (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (7d - Recovered/Resolved - )			
EU-EC- 10010816807		Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Depressed mood (n/a - Unknown - ), Dysmenorrhoea (n/a	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	IRON [IRON] (C - n/a - n/a - ), [DESLORATADINE] (C - Seasonal allergy - n/a - [n/a -	<u>ICSR</u>
										- Unknown - ), Fatigue (n/a -		n/a - n/a]), [ETHINYLESTRADIOL,	
										Unknown - ), Heavy menstrual bleeding (n/a - Recovering/Resolving		LEVONORGESTREL] (C - Dysmenorrhoea, Menometrorrhagia - n/a - [n/a - n/a - n/a])	
										Menstruation irregular (n/a - Unknown - ),			
										Polymenorrhoea (n/a - Unknown - )			
EU-EC- 10010818108		Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angina pectoris (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	[LISDEXAMFETAMINE DIMESYLATE] (C - Attention deficit hyperactivity disorder - n/a - [93d - n/a - Oral])	ICSR
										Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Dyspnoea at rest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Extrasystoles (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Heart rate irregular (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pulmonary pain (n/a - Not Recovered/Not Resolved -			

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										Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not			
										Resolved - Caused/Prolonged Hospitalisation),			
										Sensation of foreign body (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Tearfulness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10010818167		Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ),		AERIUS [DESLORATADINE] (C - Seasonal allergy - n/a - [n/a - n/a - Oral]),	<u>ICSR</u>
										Asthenia (n/a - Not Recovered/Not Resolved - ),		[BETULA VERRUCOSA POLLEN] (C - Seasonal allergy - n/a - [n/a - n/a - Subcutaneous]),	
										Fatigue (n/a - Not Recovered/Not Resolved - ),		[PHLEUM PRATENSE POLLEN] (C - Seasonal allergy - n/a - [n/a - n/a - Subcutaneous])	
										Headache (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010818168		Spontaneous			Not available	12-17 Years	Not Specified	Female		Malaise (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Nausea (n/a - Not Recovered/Not Resolved - ),			
511.50	04 /40 /0004					10.17				Vomiting (n/a - Unknown - )			1000
EU-EC- 10010818195		Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	маю		Cough (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - )			
EU-EC- 10010818546		Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
				Area						Headache (n/a - Not Recovered/Not Resolved - ),	n/a])		
										Lethargy (n/a - Not Recovered/Not Resolved - ),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - ),			
										Vaccination site reaction (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010818553		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Feeling cold (n/a - Not Recovered/Not Resolved - ),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010818584		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Fatigue (n/a - Not Recovered/Not Resolved - ),	· 4 = 11		
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Myalgia (n/a - Not Recovered/Not Resolved - ),			
										Nausea (n/a - Not Recovered/Not Resolved - ),			

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										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010818585	01/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling abnormal (n/a - Unknown - ), Pallor (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Syncope (n/a - Unknown - Other Medically Important Condition),			
EU-EC-	01/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Tremor (n/a - Unknown - ) Chest pain (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010818587	01,12,2021	Sportaneous	Professional	European Economic Area	available	Years	Specified	ridic		Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	not reported	1001
										- ), Heart rate irregular (n/a - Recovering/Resolving - ),			
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010818608	01/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyskinesia (n/a - Unknown - ), Pallor (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010818611	01/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Nasal congestion (n/a - Recovered/Resolved With Sequelae - ),			
										Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved			
										- ), Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010818621	01/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (10d - Recovered/Resolved With Sequelae - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (10d - Recovered/Resolved With Sequelae - Other Medically Important Condition)			
EU-EC- 10010818623	01/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pancreatitis acute (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pleural effusion (n/a - Not Recovered/Not Resolved - ), Pneumonia (n/a -			
EU-EC-	01/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010818636	32, 12, 2021	Sportaneous		Economic Area	available	Years	, woresterit	, idic		Unknown - Other	(S - n/a - n/a - [n/a - n/a - Intramuscular])		<u>IWR</u>
										(n/a - Unknown -			

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										Other Medically Important Condition)			
EU-EC- 10010818912	01/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arrhythmia (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSI
										Chest pain (n/a - Not Recovered/Not Resolved - ),			
										Headache (n/a - Not Recovered/Not Resolved - ),			
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - ),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - ),			
										Pericarditis (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved			
EU-EC- 10010818937		Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		ICSF
EU-EC- 10010818996	01/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Contusion (n/a - Unknown - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010819026	01/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSI
										Blood pressure decreased (524min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Bradycardia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Discomfort (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Dysphoria (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Erythema (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Fall (524min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Heart rate decreased (1d -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Loss of consciousness (524min -			

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										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Orthostatic hypotension (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pallor (524min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Presyncope (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	01/12/2021	Spontaneous	Healtheare	Non	Not	12-17	Not	Male	No	Rash (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation) Bradycardia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
100108190		Spontaneous		European Economic Area	available		Specified	Male	INO	Recovered/Resolved - Other Medically	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSK
EU-EC- 100108191		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 30ug - n/a])	Not reported	ICSR
										Myocarditis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 100108192		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (2d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	[DESLORATADINE] (C - n/a -	ICSR
										Headache (2d - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition),			
										Vaccination site pain (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 100108194		Spontaneous	Non Healthcare Professional	European Economic Area	Not available		Not Specified	Female	No	Heavy menstrual bleeding (14d - Recovering/Resolving - ), Heavy menstrual	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										bleeding (n/a - Recovering/Resolving - ),			
										Menstruation delayed (n/a - Recovering/Resolving - ),			
										Myalgia (2d - Recovered/Resolved - ),			
										Nausea (1d - Recovered/Resolved - ),			
EU-EC-	01/12/2021	Spontaneous	Non	Non	Not	12-17	Not	Female		Pyrexia (2d - Recovered/Resolved - ) Influenza (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
100108195			Healthcare Professional	European Economic Area	available	Years	Specified			Unknown - ), Ulcer (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Ulcer haemorrhage (n/a - Unknown - Other Medically Important Condition),			
										Vaginal cyst (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaginal ulceration			

		I	I	ı	I	I	I	1		(n/a - Unknown -	1	1	ı
										Other Medically Important Condition)			
EU-EC- 10010819516	01/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Peripheral swelling (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010819529	01/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
EU-EC-	01/12/2021	Spontaneous	Haaltheara	Non	Not	12-17	Not	Male	No	Pallor (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) Syncope (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICCI
10010819543	01/12/2021	Sportaneous	Professional		available	Years	Specified	Male	INO	Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10010819546	01/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSI
										Axillary pain (n/a - Unknown - Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown - ),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10010819548	01/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Facial paralysis (462min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Subcutaneous])	Not reported	ICS
										Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hypoaesthesia (5105min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Incorrect route of product administration (n/a - Unknown - ),			
										Muscular weakness (5567min - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Odynophagia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Paralysis (82h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Paresis (5567min - Recovered/Resolved - Caused/Prolonged Hospitalisation,			

										Other Medically Important Condition)			
10010819570		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)		·	ICS
EU-EC- 10010819941	01/12/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010819988	01/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (n/a - Recovering/Resolving -), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Recovering/Resolving			
EU-EC- 10010819999	01/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Unknown - ), Menstruation delayed	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10010820024	01/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(n/a - Unknown - )  Heavy menstrual bleeding (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										Menstrual disorder (n/a - Unknown - ),			
										Menstruation irregular (n/a - Unknown - )			
EU-EC- 10010820027	01/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypomenorrhoea (n/a - Unknown - ), Menstrual disorder	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
										(n/a - Unknown - ),  Menstruation delayed (n/a - Unknown - ),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved - )			
EU-EC- 10010820054	01/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Nausea (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Vaccination site pain (1d - Recovered/Resolved -)	-		
EU-EC- L0010820386	01/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Deafness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
										Tinnitus (n/a - Not Recovered/Not Resolved - )			
EU-EC- L0010820498	01/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Epistaxis (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
										Gastrointestinal haemorrhage (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Thrombocytopenia (n/a - Recovered/Resolved - Other Medically			
EU-EC-	01/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Important Condition) Arthritis (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICS
10010820585 EU-EC-	01/12/2021	Spontaneous	Professional	Economic Area Non	available Not	Years	Not	Male	No	Recovering/Resolving - Caused/Prolonged Hospitalisation) Bradycardia (n/a -	(S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) COMIRNATY [TOZINAMERAN]	Not reported	ICS
10010820716	01,12,2021	oponiani sodo		European Economic Area	available	Years	Specified			Recovering/Resolving - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	not reported	
										Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10010820724	01/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature abnormal (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Confusional state (n/a - Recovering/Resolving - Other Medically			
										Important Condition),  Fatigue (n/a - Unknown - Other Medically Important			
										Condition),  Headache (n/a -			
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										o Lioung report			
										Recovering/Resolving - Other Medically Important Condition),			
										Hypoaesthesia (2d - Recovered/Resolved - Other Medically Important Condition),			
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (4d			
										Recovered/Resolved - Other Medically Important Condition),			
										Paralysis (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10010820756	01/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Multisystem inflammatory syndrome in children (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		ICSR
EU-EC- 10010820886		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10010820949	01/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hot flush (n/a - Recovering/Resolving - ), Vaccination site pain (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10010820970	01/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Loss of consciousness (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Musculoskeletal stiffness (1d - Recovered/Resolved - ),			
										Tremor (1d - Recovered/Resolved - ), Vomiting (1d - Recovered/Resolved			
EU-EC-	01/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	-)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10010821135	01/12/2021	Sportaneous	Healthcare Professional	Economic	available	Years	Adolescent	Temake		Recovering/Resolving	(S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	not reported	ICOK
										Malaise (n/a - Recovering/Resolving -), Menstrual disorder			
										(n/a - Recovering/Resolving - ),			
										Vomiting (n/a - Recovering/Resolving - )			
EU-EC- 10010821164	01/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU EO	04/42/555	Consti	Non		Not	42.4=				Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMPANY (750-750-750-750-750-750-750-750-750-750-	No.	705-
EU-EC- 10010821227		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])		ICSR
EU-EC- 10010821266		Spontaneous	Professional	Area	Not available	12-17 Years	Adolescent		No	Malaise (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10010821294	01/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

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