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				Primary							Suspect/interacting	Concomitant/Not	Т
EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC- 10011307875	19/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011308360	19/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	applicable - [1d - n/a - n/a])		
EU-EC- 10011308390	19/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypoaesthesia (n/a - Recovering/Resolving - Other Medically Important Condition),		Not reported	ICSR
										Vaccination site pain (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011308402	19/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Angina pectoris (n/a - Recovering/Resolving - Other Medically Important Condition),	n/a - Intramuscular])		
										Chest discomfort (n/a - Recovering/Resolving -),			
										Chest pain (n/a - Recovering/Resolving -), Chills (n/a -			
										Recovering/Resolving -), Diarrhoea (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -)			
EU-EC- 10011308489	19/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -)	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
EU-EC- 10011309228	19/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Not Specified	Yes	Cystatin C increased (n/a - Unknown -)	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011309241	19/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diffuse alopecia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011310139	19/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac flutter (3d - Recovered/Resolved - Other Medically Important Condition),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - n/a - n/a - [1d - n/a - n/a])	ICSR
ttns://dan.er		/-		204						Chest pain (3d - Recovered/Resolved - Other Medically Important			1/7

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										Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Off label use (n/a - Unknown -),			
										Pain (n/a - Unknown - Other Medically Important Condition),			
										Palpitations (3d - Recovered/Resolved - Other Medically Important Condition),			
										Product use issue (n/a - Unknown -),			
										Tachycardia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 1001131024		Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Other Medically Important Condition),	- COVID-19 immunisation - Not	[ALFACALCIDOL] (C - Renal failure - n/a - [n/a - n/a - n/a]),	ICSR
										Decreased appetite (n/a - Unknown - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Blood pressure measurement - n/a - [n/a - n/a - n/a]),	
										Decreased interest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),		[LISINOPRIL, LISINOPRIL DIHYDRATE] (C - Blood pressure measurement - n/a - [n/a - n/a - n/a])	
										Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Lethargy (n/a - Unknown - Other Medically Important Condition),			
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 1001131024		Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
				Area						Dizziness (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - n/a - n/a])		
										Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 1001131054		Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (2d - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	[METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - 25mg	ICSR
										Fatigue (n/a - Unknown -),	applicable - [1d - n/a - n/a])	- n/a])	
										Gingival bleeding (1d - Recovered/Resolved			
										-), Haemorrhage (2h - Recovered/Resolved			
										- Other Medically Important Condition),			

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										Mouth ulceration (n/a - Unknown -),			
										Stomatitis (5d - Recovered/Resolved -)			
EU-EC- 10011310870	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011310871	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011310945	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (9d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Pyrexia (9d - Recovering/Resolving -)			
EU-EC- 10011310976	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011311260	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Decreased appetite (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Limb discomfort (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011311321	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not reported	ICSF
EU-EC- 10011312477	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10011312563	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Paraesthesia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011312574	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
EU-EC- 10011312658	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011312671	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Influenza (4d - Recovered/Resolved -), Injection site pain (5d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Nausea (1d - Recovered/Resolved			
EU-EC- 10011312672	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Fatigue (2d - Recovered/Resolved -),			
										Headache (0d - Recovered/Resolved -),			
										Injection site pain (0d - Recovered/Resolved -),			
										Injection site swelling (2d - Recovered/Resolved -),			
										Limb discomfort (1d - Recovered/Resolved -),			
										Malaise (1d - Recovered/Resolved -),			
										Myalgia (0d - Recovered/Resolved -),			

30.11.2022 1	1.23							Kull Lii	IE LIS	ung Report			
										Nausea (0d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10011312675	19/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	Not reported	ICSR
										Dizziness (0d - Recovered/Resolved -),	- [n/a - n/a - n/a])		
										Dyspnoea (0d - Recovered/Resolved -),			
										Fatigue (2d - Recovered/Resolved -),			
										Headache (3d - Recovering/Resolving -),			
										Injection site pain (1d - Recovering/Resolving -),			
										Limb discomfort (1d			
										Recovered/Resolved -),			
										Lymphadenopathy (3d -			
										Recovering/Resolving -),			
										Pyrexia (3d - Recovering/Resolving -),			
										Tachycardia (0d - Recovered/Resolved -)			
EU-EC- 10011312704	19/01/2022	Spontaneous	Healthcare	Economic	Not available	12-17 Years	Adolescent	Female	No	Chills (2d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S	Not reported	<u>ICSR</u>
			Professional	Area						Resolved -), Fatigue (2d - Not Recovered/Not Resolved -),	- Immunisation - n/a - [n/a - n/a - n/a])		
										Headache (3d - Not Recovered/Not Resolved -),			
										Lymphadenopathy (1d - Recovered/Resolved -),			
										Myalgia (2d - Not Recovered/Not Resolved -),			
										Pyrexia (2d - Not Recovered/Not Resolved -)			
EU-EC- 10011312711	19/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Chills (2d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (2d - Not Recovered/Not Resolved -),	[-4444444444444		
										Headache (3d - Not Recovered/Not Resolved -),			
										Lymphadenopathy (1d - Recovered/Resolved -),			
										Myalgia (2d - Not Recovered/Not Resolved -),			
										Pyrexia (2d - Not Recovered/Not Resolved -)			
EU-EC- 10011312731	19/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Chills (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Influenza (2d - Recovered/Resolved -),	[145 140 140])		
										Injection site pain (3d - Recovered/Resolved			

30.11.2022 1	7.23							Run Li	ne Lis	ting Report			
										-), Limb discomfort (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)			
EU-EC- 10011312953	19/01/2022	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	- Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - n/a - Intramuscular])	Not reported	ICSR
										Cough (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),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Urinary tract inflammation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011313217	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Acid base balance abnormal (n/a - Recovering/Resolving	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICSR
										-), Headache (n/a - Recovering/Resolving -), Tremor (n/a -	MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - n/a -		
EU-EC-	19/01/2022	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Recovering/Resolving -) Vaccination failure	[n/a - n/a - Intramuscular]) COMIRNATY	Not reported	ICSR
10011313368	-5, 0-1, -0-1	-			available	Years	Specified			(n/a - Recovering/Resolving -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])		
EU-EC- 10011313774	19/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Recovering/Resolving - Other Medically Important Condition), Chest discomfort	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported	ICSR
										(n/a - Recovering/Resolving - Other Medically Important Condition),			
										Discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),			
EU-EC-	19/01/2022	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition) Haemoglobin	COMIRNATY	Not reported	ICSR
10011313787	, ~_, ~~,		Professional		available	Years	Specified	Salar		decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		2001
										Thrombocytopenia (n/a - Recovering/Resolving			

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										- Caused/Prolonged Hospitalisation)			
EU-EC- 10011313822	19/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d]	Not reported	ICSR
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	n/a - Unknown])		
EU-EC- 10011313826	19/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSF
										Hyperhidrosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain (n/a -	n/a - n/a])		
EU-EC-	10/01/2022	Chantanaous	Lionithenro	Non	Not	12.17	Not	Male	No	Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIDNATY	Net reported	ICCE
10011313837	19/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Маїе	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL -	Not reported	ICSR
										Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Dyspepsia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Hernia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nephrotic syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011313871	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved -), Headache (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSF
										Recovered/Resolved -), Heavy menstrual bleeding (14d -	1{DF} - n/a])		
										Recovered/Resolved -), Injection site			
										erythema (2d - Recovered/Resolved -), Injection site			
										inflammation (2d - Recovered/Resolved -), Injection site pain			
										(2d - Recovered/Resolved -), Malaise (2d -			
										Recovered/Resolved			
EU-EC- 10011313893	19/01/2022	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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										bleeding (n/a - Not Recovered/Not Resolved -)	1{DF} - n/a])		
EU-EC- 10011314317	19/01/2022	Spontaneous	Non Healthcare Professional	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	ICSR
										Rash (6d -			

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										Recovered/Resolved -)			
EU-EC- 10011314372	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (0d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011314485	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site erythema (7d - Recovering/Resolving -), Injection site pain (4d - Recovered/Resolved -), Injection site swelling (7d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011314512	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-), Vaccination site reaction (7d - Recovering/Resolving -) Headache (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	Not reported	ICSR
										Injection site pain (1d - Recovered/Resolved -)	- [n/a - n/a - n/a])		
EU-EC- 10011314575	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Not Recovered/Not Resolved -), Dizziness (1d - Unknown -), Fatigue (2d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (1d - Not Recovered/Not Resolved -), Influenza (1d - Not Recovered/Not Resolved -), Injection site			
										erythema (1d - Not Recovered/Not Resolved -), Injection site swelling (1d - Not Recovered/Not Resolved -), Pyrexia (1d - Not			
EU-EC- 10011314619	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Not Resolved -) Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	Not reported	ICSR
										Injection site pain (32d - Recovered/Resolved	- [n/a - n/a - n/a]) [°]		
EU-EC- 10011314675	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011314689	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011314857	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY	Not reported	ICSR
EU-EC- 10011314918	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (36h - Recovered/Resolved -), Influenza like illness (36h - Recovered/Resolved -), Pain in extremity (36h - Recovered/Resolved -), Pyrexia (36h -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

		Recovered/Resolved -)
19/01/2022 Spontane	taneous Healthcare Professional Economic Area Not Rears	Male No Deep vein thrombosis (vi) - Recovering/Resolved Coulstand Proteoring of thrombosis (vi) - Recovering/Resolved Coulstand Proteoring of thosphalesistin), in International Coulstand Proteoring of the P

10.11.2022 1										ting report			
EU-EC- 10011315198	19/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Encephalitis viral (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	AND ALUMINIUM PHOSPHATE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED AND ALUMINIUM PHOSPHATE, PERTUSSIS FILAMENTOUS FILAMENTOUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), POLIOVIRUS (INACTIVATED) TYPE 1 (MEF-1 STRAIN)	
										Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011315201	19/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pallor (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving			
EU-EC-	19/01/2022	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	- Other Medically Important Condition) Syncope (n/a -	COMIRNATY	Not reported	ICSR
10011315234			Professional	European Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10011315239	19/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Blood pressure systolic decreased (n/a - Recovered/Resolved -), Loss of consciousness (715min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved - Other Medically			
EU-EC- 10011315258	19/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Hyperhidrosis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
EU-EC-	19/01/2022	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Chest pain (n/a -	COMIRNATY	Not reported	ICSR

0.11.2022 1	1.23							IXUII L	He LIS	aing Report			
10011315360			Professional	European Economic Area	available	Years	Specified			Recovering/Resolving - Caused/Prolonged Hospitalisation), Cold sweat (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Resolving - Caused/Prolonged Hospitalisation), Respiration abnormal (n/a - Recovering/Resolving	- COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])		
EU-EC- 10011315377	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Caused/Prolonged Hospitalisation) Decreased appetite (2d - Recovered/Resolved -), Insomnia (n/a - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (12h - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011315794	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blindness transient (10min - Recovered/Resolved - Other Medically Important Condition), Emotional distress (n/a - Not Recovered/Resolved - Other Medically Important Condition), Emotional distress (n/a - Not Recovered/Resolved - Other Medically Important Condition), Feeling cold (10min - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (10min - Recovered/Resolved - Other Medically Important Condition), Muscular weakness (n/a - Recovered/Resolved - Other Medically Important Condition), Muscular weakness (n/a - Recovered/Resolved - Other Medically Important Condition), Oxygen saturation decreased (10min - Recovered/Resolved - Other Medically Important Condition), Presyncope (10min - Recovered/Resolved - Other Medically Important Condition), Presyncope (10min - Recovered/Resolved - Other Medically Important Condition), Tachycardia (10min - 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- 10011315866	19/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Headache (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
EU-EC- 10011315876	19/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Life Threatening), Chills (n/a - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>

0.11.2022 1	1.23							Rull Li	He LIS	ung Report			
										- Life Threatening), Contusion (n/a - Recovered/Resolved - Life Threatening),			
										Headache (n/a - Recovered/Resolved - Life Threatening),			
										Pyrexia (n/a - Recovered/Resolved - Life Threatening),			
										Rhinorrhoea (n/a - Recovered/Resolved - Life Threatening),			
EU-EC-	10/01/2022	Spontaneous	Non	Non	Not	12-17	Not	Male	No	Somnolence (n/a - Recovered/Resolved - Life Threatening) Decreased appetite	COMIRNATY	Not reported	ICCD
10011315887	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	available	Years	Specified	Маје	NO	(n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Lymphadenopathy (20d - Recovered/Resolved - Other Medically Important Condition),			
										Musculoskeletal discomfort (n/a - Unknown - Other Medically Important Condition),			
										Musculoskeletal stiffness (n/a - Unknown - Other Medically Important Condition),			
										Peripheral swelling (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011316085	19/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Uveitis (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- 10011316087	19/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Uveitis (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
EU-EC- 10011316135	19/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood glucose abnormal (n/a - Unknown -), Blood pressure	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	[VITAMIN D] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
										decreased (0d - Recovered/Resolved -),	n/a - Intramuscular])		
										Cyanosis (0d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011316147	19/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
EU-EC- 10011316287	19/01/2022	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not reported	ICSR
EU-EC- 10011316315	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} -	Not reported	ICSR
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	n/a])		
										Palpitations (n/a -			

0.11.2022 1	7.23							Run Li	ine Lis	ting Report			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pericardial effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011316506	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling),	n/a - n/a])		
										Headache (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC- 10011316752	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011316793	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Gingival bleeding (4d - Recovered/Resolved - Other Medically Important Condition), Gingival pain (4d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 2{DF} - Intramuscular])	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011316817	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	COMIRNATY [TOZINAMERAN] (C - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular])	ICSR
										Wrong schedule (1d - Recovered/Resolved -)	1{DF} - Intramuscular])		
EU-EC- 10011316907	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Oedema peripheral (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011316961	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011317009	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
EU-EC- 10011317112	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (9d - Recovered/Resolved - Other Medically Important Condition), Heart rate increased	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										(9d - Recovered/Resolved -), Heart rate irregular (9d -			
EU-EC- 10011317171	19/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Recovered/Resolved -) Amenorrhoea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
10011317171			Professional		avaliable	leais				Resolved -)	- COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10011317246	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Recovering/Resolving -), Chills (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovering/Resolving -), Fatigue (n/a			
										Recovering/Resolving -), Heavy menstrual			
										bleeding (n/a -			

).11.2022 1	7.23							Run L	ine Lis	sting Report			
										Recovering/Resolving -),			
										Malaise (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011317340	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (3d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011317489	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Visual impairment (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011318006	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011318150	19/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Immunisation reaction (n/a - Recovering/Resolving - Other Medically Important Condition),	Intramuscular])		
										Palpitations (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Respiratory tract congestion (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011318223	19/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011318714	19/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Unknown - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Musculoskeletal pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Neck pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011318834	19/01/2022	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adult	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	ICSR
EU-EC- 10011318944	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),	Unknown - [n/a - 1{DF} - n/a])		
										Nausea (n/a - Not Recovered/Not			

30.11.2022 1	7.23							Run Li	ine Lis	ting Report			
										Resolved -), Ocular hyperaemia (n/a - Not Recovered/Not			
EU-EC- 10011318955	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved -), Pallor (n/a - Not Recovered/Not Resolved -) Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose	Not reported	ICSR
										Nasopharyngitis (n/a - Not Recovered/Not Resolved -)	not changed - [n/a - 1{DF} - n/a])		
EU-EC- 10011318957	19/01/2022	Spontaneous	Healthcare Professional	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 - Unknown])	Not reported	ICSR
										Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),	.,,,		
										Palpitations (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011318978	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Atrial fibrillation (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Circulatory collapse (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10011318980	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011319007	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011319012	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ANHYDROUS FUSIDIC ACID, FUSIDIC ACID, FUSIDIC ACID HEMIHYDRATE, FUSIDIC ACID PENTAHYDRATE] (C - Eye infection - n/a - [n/a - n/a - Ophthalmic])	ICSR
EU-EC- 10011319022	19/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
EU-EC- 10011319282	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Amnesia (n/a - Recovering/Resolving -), Cognitive disorder (n/a - Recovering/Resolving -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011319380	19/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Cough (n/a - Recovered/Resolved -), Oropharyngeal pain	Intramuscular])		
										(n/a - Recovered/Resolved -), Pain (n/a -			
										Recovered/Resolved -), Pyrexia (n/a -			
										Recovered/Resolved -), Vaccination failure			
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										(n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011319413	19/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSF
										Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Palpitations (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011319432	19/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Recovered/Resolved -), Chest pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),			
										Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011319490	19/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Unknown -), Heart rate increased (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										- Other Medically Important Condition)			
EU-EC- 10011319698		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Herpes zoster (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011319701	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not reported	ICSR
										Recovered/Not Resolved -), Influenza like illness (1d -			
										Recovered/Resolved -), Weight bearing difficulty (n/a - Not			
										Recovered/Not Resolved -)			
EU-EC- 10011319782	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),		COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICSR
										Vaccination failure (n/a - Recovered/Resolved -)			
EU-EC- 10011319835	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged			

30.11.2022 1	7.23							Run Li	ne Lis	ting Report			
										Hospitalisation), Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	19/01/2022	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY	Not reported	ICSR
10011319861			Healthcare Professional	Economic Area	available	Years				Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), COMIRNATY		
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])		
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011319864	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (0d - Recovered/Resolved - Other Medically Important Condition),		COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICSR
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011319893	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011319916	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Fatigue (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011319922	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011320038	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (2d - Recovered/Resolved -), Fatigue (3d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Headache (3d - Recovered/Resolved			
										-), Injection site pain (6d - Recovering/Resolving -),			
										Myalgia (2d - Recovered/Resolved			
EU-EC- 10011320089	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -), Fatigue (3d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Headache (3d - Recovered/Resolved -),			
										Influenza (2d - Recovered/Resolved -),			
										Injection site pain (2d - Unknown -),			
										Lymphadenopathy (2d - Recovered/Resolved -),			
EU EO	10/04/222	Consti	New	F	Note	12.1=	Ada	M-1	N.	Nausea (1d - Recovered/Resolved -)	COMPLIANT	Not were to	100-
EU-EC- 10011320096	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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										Injection site pain (1d - Recovered/Resolved -)			
EU-EC- 10011320111	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (2d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										-), Headache (2d - Recovered/Resolved			
										Injection site pain (3d - Recovered/Resolved			
										Nausea (1d - Recovered/Resolved -)			
EU-EC- 10011320138	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (46d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011320146	19/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (9d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Dizziness (16d - Unknown -),	- [11/a - 11/a - 11/a])		
										Injection site pain (1d - Unknown -), Tachycardia (9d -			
EU-EC-	18/01/2022	Spontaneous	Non	European	Not	12-17	Not	Male	No	Unknown -) Head discomfort (n/a	COMIRNATY	Not reported	ICSF
10011293245	, ,	·	Healthcare Professional	Economic	available	Years	Specified			Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	·	
										Lymphadenopathy (n/a - Recovered/Resolved -),	[-,,(, -,,-],		
										Pain in extremity (n/a - Recovered/Resolved			
										-), Pyrexia (n/a -			
ELL EC	10/01/2022	C	1114	F	Net	12.17	Net	N4-1-	NI-	Recovered/Resolved	COMIDNIATY	Net was sited	TOCI
EU-EC- 10011293283	18/01/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotension (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICS</u>
EU-EC-	18/01/2022	Spontaneous	Non	European	Not	12-17	Not	Male	No	Presyncope (0d - Recovered/Resolved -) Headache (n/a -	applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSF
10011293611	10/01/2022	эропшпсоиз	Healthcare Professional	Economic	available	Years	Specified	i i i i i		Recovering/Resolving -), Pyrexia (n/a -		Not reported	1001
										Recovering/Resolving -)	, , , ,		
EU-EC- 10011293675	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSF
										Chest pain (n/a - Not Recovered/Not Resolved -),	applicable - [n/a - 30ug - Intramuscular])		
										Hyperamylasaemia (n/a - Not Recovered/Not Resolved -),			
										Hyperlipasaemia (n/a - Not Recovered/Not Resolved -),			
										Lymphadenitis (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011293690	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10011293694	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (0d - Recovered/Resolved -), Pallor (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSI
										Recovered/Resolved -),	.3mL - Intravenous (not otherwise specified)])		

J.11.2022 I	7.20	I	I	ı	ı		ı	1	1	sung Report	I	ı	1
										Recovered/Resolved -)			
EU-EC- 10011294121	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Insomnia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011294187	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011294372	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (20d - Recovered/Resolved - Other Medically Important Condition), Arthritis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Back pain (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Resolved - Other Medically Important Condition),			
										Dysgraphia (n/a - Unknown -), Fine motor skill dysfunction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Insomnia (n/a - Unknown -), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important			
										Condition), Quality of life decreased (n/a - Unknown -)			
EU-EC- 10011294375	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011294380	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (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- 10011294385	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (33min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011294387	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC- 10011294388	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
EU-EC- 10011294392	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (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- 10011294395	18/01/2022	Spontaneous	Healthcare Professional	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

.11.2022 1	7.20							I (uii L	IIIC LIS	ling Report			
EU-EC- 10011294397	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pemphigoid (n/a - Recovering/Resolving - Other Medically Important Condition), Rash (n/a - Recovering/Resolving - Other Medically	- COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10011294403	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Abdominal pain upper (224h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICS
										Vomiting (224h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	Intramuscular])		
EU-EC- .0011294404	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
U-EC- 0011294410	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (18min - Recovered/Resolved -), Syncope (3min - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
:U-EC- 0011294411	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
:U-EC- 0011294412	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (30min - Recovered/Resolved -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011294416	18/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovered/Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Insomnia (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)		FLUENZ TETRA [A/GUANGDONG- MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE STRAIN (A/HAWAII/66/2019, MEDI 326775), A/HONG KONG/2671/2019 (H3N2) - LIKE STRAIN (A/HONG KONG/2671/2019, MEDI 325078), B/PHUKET/3073/2013 - LIKE STRAIN (B/HUKET/3073/2013, MEDI 325078), B/PHUKET/3073/2013, MEDI 306444), B/WASHINGTON/02/2019 - LIKE STRAIN (B/WASHINGTON/02/2019, MEDI 323797), A/TEXAS/50/2012 (H3N2)- LIKE STRAIN (A/TEXAS/50/2012, MEDI 237514), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012, MEDI 237751), A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/BRISBANE/60/2008, MEDI 237751), A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/BRISBANE/60/2008, MEDI 228030, B/BRISBANE/60/2008, B	,

.11.2022 1	1.23							Rull Li	He LIS	ung Report			
	19/04/2022	Coortes	L oalth or	Neg	Not	12.17	Not	Mala	No	Blood pressure	COMIDNATY	MEDI 254977), A/MICHIGAN/45/2015 (H1N1)PDM09 - LIKE STRAIN (A/SLOVENIA/2903/2015, MEDI 279432), A/SINGAPORE/INFIMH-16- 0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16- 0019/2016, MEDI 291690), B/COLORADO/06/2017-LIKE STRAIN (B/COLORADO/06/2017, MEDI 293454)] (C - Influenza immunisation - n/a - [n/a - n/a - n/a]) Not reported	
EU-EC- 10011294426	18/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	increased (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011294672	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (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- 10011294689		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Adolescent		No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition)	[IBUPROFEN, IBUPROFEN SODIUM] (S - Headache - Unknown - [n/a - n/a - Unknown]), [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011294690	18/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Exposure to contaminated device (n/a - Unknown -), Poor quality product administered (n/a - Unknown -), Product contamination (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011294739	18/01/2022	Spontaneous		Non European Economic Area	Not available		Not Specified	Male	No	Abdominal pain (17h - Recovered/Resolved - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Gait disturbance (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Pallor (n/a - Unknown - Other Medically Important Condition), Pelvic pain (17h - Recovered/Resolved - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Other Medically Important Condition), Urinary tract infection bacterial (n/a - Unknown -			

J.11.2022 I	7.20							IXUII LI	HE LI	sung Report			
										Other Medically Important Condition)			
EU-EC- 10011294746	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011294750	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Recovered/Resolved - Caused/Prolonged Hospitalisation)	Intramuscular])		
EU-EC- 10011294761	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Vision blurred (n/a - Unknown -)	Intramuscular])		
EU-EC- 10011294763	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chemical poisoning (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Vaccination site pain (n/a - Unknown -)	Intramuscular])		
EU-EC- 10011294766	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (45min - Recovered/Resolved -), Syncope (45min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										- Other Medically Important Condition)	Intramuscular])		
EU-EC- 10011294894	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),	[TOZINAMERAN] (S	CERVARIX [HUMAN PAPILLOMAVIRUS TYPE 16 L1 PROTEIN, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN, MONOPHOSPHORYL LIPID A, HUMAN PAPILLOMAVIRUS TYPE 16 L1 PROTEIN	ICSR
										Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),		ADJUVANTED BY AS04 ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED PRODUCED ON BACULOVIRUS HI-5 RIX4446 CELLS, TRICHOPLUSIA NI. DERIVED, HUMAN	
										Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),		PAPILLOMAVIRUS TYPE 18 L1 PROTEIN ADJUVANTED BY ASO4 ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED PRODUCED ON BACULOVIRUS HI-5 RIX4446 CELLS, TRICHOPLUSIA NI.	
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),		DERIVED, ALGELDRATE, MONOPHOSPHORYL LIPID A, HUMAN PAPILLOMAVIRUS TYPE 16 L1 PROTEIN, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN, ALGELDRATE] (C -	
										Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),		Immunisation - n/a - [n/a - n/a - Intramuscular]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - Oral]),	
										Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)		[PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a - [n/a - n/a - Oral])	
EU-EC- 10011295219	18/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S	Not reported	<u>ICSR</u>
				Economic Area						Haematemesis (n/a - Unknown - Other Medically Important Condition),	- COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
										Loss of consciousness (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011295220	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Appendicitis (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- 10011295228	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Hypothermia (n/a -	COMIRNATY	Not reported	ICSR

).11.2022 1	7.20							IXUII L	IIIE LI	sting Report			
										Recovering/Resolving - Other Medically Important Condition),	n/a - Intramuscular])		
										Vaccination site pain (n/a - Recovering/Resolving -)			
EU-EC- 10011295266	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (40min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Loss of consciousness (1min	applicable - [1d - n/a - Intramuscular])		
										Recovered/Resolved - Other Medically Important Condition)	2,		
EU-EC- 10011295279	18/01/2022	Spontaneous	Healthcare Professional	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 - [n/a - n/a - Unknown])	Not reported	ICSR
										Chest pain (n/a - Unknown - Other Medically Important Condition),	n/a - Unknown])		
										Dizziness (n/a - Unknown - Other Medically Important Condition),			
										Dyspnoea (n/a - Unknown - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important Condition),			
										Rhinorrhoea (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011295685	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia (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
EU-EC- 10011295690	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	n/a - Intramuscular])		
EU-EC- 10011295710	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011295719	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
										Chills (n/a - Recovering/Resolving - Other Medically Important Condition),	,		
										Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
FILE C	10/04/2025	Coord	Haalit.	New	Net	12.45	Net	F	NI:	Palpitations (n/a - Recovering/Resolving - Other Medically Important Condition)		Not seemed !	Toes
EU-EC- 10011295720	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

										Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Neuralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
ELL EQ	10/04/2022					12.47				Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMPUTATION		Trock and the state of the stat
EU-EC- 10011295725	18/01/2022	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),	mu amusculai j		
										Respiration abnormal (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011295729	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (20min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011295764	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	applicable - [1d - n/a - Intramuscular])		
										Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Strabismus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011295768	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bradycardia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
										Pallor (n/a - Recovering/Resolving - Other Medically Important Condition),	,		
										Ventricular			

										extrasystoles (n/a - Recovering/Resolving - Other Medically			
EU-EC- 10011295773	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Aggression (n/a - Recovering/Resolving - Other Medically Important Condition), Body temperature abnormal (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Sweating fever (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Tension headache (2d - Recovered/Resolved - Other Medically			
EU-EC- 10011295775	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Vision blurred (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011295780	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -) Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011295782	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSF
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	,		
EU-EC- 10011295783	18/01/2022	Spontaneous	Healthcare Professional	Non 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 - Intramuscular])	Not reported	ICSF
										Feeling abnormal (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Feeling hot (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Hyperhidrosis (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved			

0.11.2022 1	1.23							Ruii Li	He LIS	sung Report			
										- Other Medically Important Condition),			
										Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011295790	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC- 10011296312	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Recovering/Resolving - Other Medically Important Condition), Chest discomfort (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Chest pain (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10011296323	18/01/2022	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 - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011296352	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (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- 10011296359		Spontaneous	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	ICSR
EU-EC- 10011296389	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011296400	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Muscular weakness (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
EU-EC- 10011296432	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[METOPROLOL SUCCINATE] (C - n/a - n/a - [n/a - 47.5mg - n/a])	ICSR
EU-EC- 10011296564	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-) Body temperature increased (36h - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (10h - Recovered/Resolved -), Injection site pain (10h - Recovered/Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011296588	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Facial asymmetry (n/a - Recovering/Resolving - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR

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										Condition), Hypoaesthesia (n/a - Recovering/Resolving - Other Medically	n/a - Intramuscular])		
EU-EC- 10011296608	18/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Important Condition) Wrong product administered (n/a - Unknown -), Wrong strength (n/a - Unknown -)	COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011296709	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Glomerulonephritis (n/a - Recovering/Resolving - Other Medically Important Condition), Haematuria (n/a - Recovering/Resolving - Other Medically Important Condition), Proteinuria (n/a - Recovering/Resolving - Other Medically Important Condition), Proteinuria (n/a - Recovering/Resolving - Other Medically Important Condition), Renal disorder (n/a - Recovering/Resolvi	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011296858	18/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	- Other Medically Important Condition) SARS-CoV-2 test positive (n/a - Unknown -)	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	ICSR
EU-EC- 10011296907	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Joint swelling (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011296925	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eyelid ptosis (n/a - Unknown - Other Medically Important Condition), Papilloedema (n/a - Unknown - Other Medically Important Condition), Transient ischaemic attack (n/a - Unknown - Other Medically Important Condition), Visual field defect (n/a - Unknown - Other Medically Important Condition), Visual field defect (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011296963	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011297024	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Breast pain (7d - Recovering/Resolving -), Lymphadenopathy (7d - Recovering/Resolving -)	- Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011297044	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Appendicitis (0d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Fatigue (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

0.11.2022 1										ting report			
										Injection site pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Lymphadenopathy (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	18/01/2022	Spontaneous	Non	European	Not	12-17	Child	Female	No	Vomiting (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation) Dyspnoea (n/a -	COMIRNATY	Not reported	ICSR
10011297045	10,01,2022	Spontaneous	Healthcare Professional	Economic	available	Years	Crinic	remaie		Recovering/Resolving - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	not reported	ICOK
										Formication (n/a - Recovering/Resolving - Other Medically Important Condition),	Intramuscular])		
										Gilbert's syndrome (n/a - Unknown - Other Medically Important Condition),			
										Hyperhidrosis (n/a - Recovering/Resolving -), Muscular weakness			
										(n/a - Recovering/Resolving -),			
										Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Tachycardia (n/a - Recovering/Resolving -)			
EU-EC- 10011297090	18/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (5min - Recovered/Resolved -), Dizziness (5min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										-), Headache (5min - Recovered/Resolved -)			
EU-EC- 10011297171	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (5min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011297302	18/01/2022	Spontaneous	Non Healthcare Professional	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- 10011297505	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Unknown - Other Medically Important Condition), Breast swelling (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
EU-EC- 10011297873	18/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	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	ICSR
EU-EC- 10011298570	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovered/Resolved -), Limb discomfort (1d	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

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										Recovered/Resolved			
										Malaise (1d - Recovered/Resolved -),			
										Nausea (1d - Recovered/Resolved			
EU-EC-	18/01/2022	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	-) Papilloedema (n/a -	COMIRNATY	Not reported	ICS
10011298612	10,01,2022	Sportaneous		Economic Area	available	Years	Adolescent	remale	140	Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	100
										Visual field defect (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011298617	18/01/2022	Spontaneous		European	Not	12-17 Years	Adolescent	Female	No	Eyelid oedema (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S	Not reported	ICS
.0011298017			Professional	Economic Area	available	rears				Medically Important Condition),	- Immunisation - n/a - [n/a - n/a - n/a])		
										Papilloedema (n/a - Unknown - Other Medically Important Condition),			
										Visual field defect (n/a - Unknown - Other Medically Important Condition)			
	18/01/2022	Spontaneous		European	Not	12-17	Adolescent	Male	No	Feeling hot (n/a -	COMIRNATY	Not reported	ICS
10011298621			Healthcare Professional	Economic Area	available	Years				Recovering/Resolving -), Injection site pain	- Immunisation - n/a - [n/a - n/a - n/a])		
										(n/a - Recovering/Resolving -),			
										Nausea (n/a - Recovering/Resolving -)			
EU-EC- 10011298736	18/01/2022	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 - 2{DF} - n/a])	Not reported	ICSF
EU-EC- 10011299524	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash pruritic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011299540	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dermatitis allergic (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Psoriasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rash papular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011299633	18/01/2022	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	Not reported	ICSF
										Vaccination failure (n/a - Unknown - Other Medically	applicable - [1d - n/a - Intramuscular])		
EU-EC-	18/01/2022	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Important Condition) Blood creatine	COMIRNATY	Not reported	ICS
10011299710	10/01/2022	Spontaneous	Professional		available	Years	Specified	riale	No	phosphokinase MB increased (n/a - Unknown -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	100
										Blood creatine phosphokinase increased (n/a - Unknown -),	applicable - [1d - n/a - Intramuscular])		
										C-reactive protein increased (n/a - Unknown -),			
										Chest discomfort (n/a - Unknown -),			
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										nospitalisation),			

Professional European Economic Area Professional Economic Area Professional European Economic Area Professional Economic Area Profession	0.11.2022 1	1.23					Ruii Li	ne Lis	aing Report			
AND THE CONTRACT OF THE CONTRA									- Other Medically Important			
PLACE 1871/2022 Spatialness Neathboard Manual Properties M												
### PAPE Market M									schedule of product administration (n/a -			
Building									Unknown - Caused/Prolonged			
Selection Security Separation Security Sec									Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important			
EDI-EC- DID 12/97/22 Fig. 18/01/2022 Spontraneous Healthcare No. Processor all Recognitions (Area Services) Area Models (Area Ser									Unknown - Caused/Prolonged			
Prefessoral European Nata Prefessoral European												
ELECT. 18/01/2022 Spontaneous Healthcare Professional Economic Constitution, Characteristical Professional Professional Economic Constitution, Characteristical Professional Economic Constitution, Characteristical Professional Professional Economic Constitution, Characteristical Professional Professional Economic Characteristical Professional Professional Economic Constitution, Characteristical Professional Professio	EU-EC- 10011299713	18/01/2022	Spontaneous	Professional	European Economic		Female	No	Recovered/Not Resolved - Caused/Prolonged	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
EU-EC- 10/01/2022 Spontaneous Healthcare Non Professional European Rose Recovered/Not Resolved refunged Hospitalisation, Other Medically Limportant Cordibute, Not Recovered/Not Resolved refunged Hospitalisation, Other Medically Limportant Rose Recovered/Not Resolved refunged Hospitalisation, Other Medically Limportant Rose Recovered/Not Resolved - Unit Professional European Rose Recovered/Not Resolved - Unit Recovered/Not Resolved - Unit Reso									Hepatic function abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged	n/a -		
ELIEC- 10011299725 18/01/2022 Spontaneous Healthcare Professional European available Professional Pr									- Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important			
EU-ECT 18/01/2022 Spontaneous Healthcare Non Professional European									Recovered/Not Resolved - Caused/Prolonged			
(n/a - Unknown - Other Medically Important Condition), Epistaxis (n/a - Unknown -), Fall (n/a - Unknown -), Febrile neutropenia (n/a - Unknown - Other Medically Important Condition), Haematoma (n/a - Unknown - Other Medically Important Condition), Haematoma (n/a - Unknown -), Malaise (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pancytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	EU-EC- 10011299725	18/01/2022	Spontaneous	Professional	European Economic		Male	No	Aplastic anaemia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
Epistaxis (n/a - Unknown -), Fall (n/a - Unknown -), Febrile neutropenia (n/a - Unknown - Other Medically Important Condition), Haematoma (n/a - Unknown -), Malaise (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pancytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),									(n/a - Unknown - Other Medically Important			
), Febrile neutropenia (n/a - Unknown - Other Medically Important Condition), Haematoma (n/a - Unknown -), Malaise (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pancytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),									Epistaxis (n/a -			
(n/a - Unknown - Other Medically Important Condition), Haematoma (n/a - Unknown -), Malaise (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pancytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),												
Haematoma (n/a - Unknown -), Malaise (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pancytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),									(n/a - Unknown - Other Medically Important			
Unknown -), Oropharyngeal pain (n/a - Unknown -), Pancytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),									Haematoma (n/a -			
(n/a - Unknown -), Pancytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),												
Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),												
									Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important			

0.11.2022 1	1.23							Rull L	IIIE LIS	sting Report			
										Unknown -), Platelet count decreased (n/a - Unknown - Caused/Prolonged Hospitalisation),			
EU-EC- 10011299767	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Unknown -) Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
EU-EC-	18/01/2022	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Unknown - Caused/Prolonged Hospitalisation) Arthralgia (n/a -	Intramuscular]) COMIRNATY	Not reported	ICSR
10011299769	10/01/2022	Sportalicous	Professional		available	Years	Specified	ridic		Unknown -), Road traffic accident (n/a - Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	not reported	<u>1001</u>
										Vaccination site pain (5h - Recovered/Resolved -)			
EU-EC- 10011299779	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Respiration abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011299780	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Multiple injuries (5min - Recovered/Resolved - Other Medically Important Condition), Road traffic accident	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										(5min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011299783	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011299787	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (3h - Recovered/Resolved -), Dyspnoea (3h - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Hypoaesthesia (3h - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011299801	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Overdose (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Pneumothorax spontaneous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	.5mL - Intramuscular])		
EU-EC- 10011299808	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -), 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- 10011299809	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

7.11.2022 1		ı	ı					, ran L		ting report	ı	1	
										Muscular weakness (n/a - Unknown -)			
EU-EC- 10011299820	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arrhythmia (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Chest discomfort (n/a - Recovered/Resolved -)			
EU-EC- 10011299831	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Embolism (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[CYPROTERONE ACETATE, ETHINYLESTRADIOL] (C - n/a - n/a - [n/a - n/a - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSF
												[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10011300006	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site erythema (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site mass (n/a - Unknown - Other Medically Important Condition),			
EU-EC-	10/01/2022	Canadanas	Non	Non	Not	12.17	Not	Melo	Ne	Vaccination site swelling (n/a - Unknown - Other Medically Important Condition)	COMIDNATY	Networked	Teer
10011300009	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eye contusion (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
										Eye swelling (2d - Recovered/Resolved - Other Medically Important Condition),	applicable - [1d - n/a - n/a])		
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Hypersensitivity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown -)			
EU-EC- 10011300329	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (26d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	Not reported	ICSF
EU-EC- 10011300338	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	- [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
EU-EC- 10011300344	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a -			

0.11.2022 1	1.23							IXUII LI	IIE LIS	ung Report			
										Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pallor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Troponin increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011300346	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	18/01/2022	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY	Not reported	ICSR
10011300349	,		Healthcare	Economic Area	available	Years				Recovering/Resolving - Caused/Prolonged	[TOZINAMERAN] (S - Immunisation - n/a		
EU-EC- 10011300350	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Chest pain (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	- [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Myocarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
										Pericardial effusion (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC- 10011300360	18/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pallor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Troponin increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011300368	18/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Pericarditis (13d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	Not reported	ICSR
EU-EC- 10011300669	18/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Pain in extremity (n/a - Recovered/Resolved -), Pyrexia (n/a -	- [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Recovered/Resolved -)	Intramuscular])		
EU-EC-	18/01/2022	Spontaneous	Non	European	Not	12-17	Not	Not	Yes	Proteinuria (n/a -	COMIRNATY	Not reported	<u>ICSR</u>

30.11.2022 1	7.23							Run Li	ne Lis	ting Report			
10011300678			Healthcare Professional	Economic Area	available	Years	Specified	Specified		Unknown -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10011300679	18/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Dermatitis acneiform (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011300681	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (n/a - Not Recovered/Not Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Rash (n/a - Not Recovered/Not Resolved -)	applicable - [1d - n/a - Intramuscular])		
EU-EC- 10011300789	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abnormal withdrawal bleeding (n/a - Not Recovered/Not Resolved -), Fatigue (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ANTICONCEPTIEPIL [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
										Recovered/Resolved -), Headache (2d - Recovered/Resolved			
										Injection site inflammation (3d - Recovered/Resolved			
										-), Injection site pain			
										(3d - Recovered/Resolved -),			
										Injection site swelling (3d - Recovered/Resolved -),			
										Malaise (3d - Recovered/Resolved -),			
										Nausea (2d - Recovered/Resolved -)			
EU-EC- 10011301006	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)	n/a - n/a])		
EU-EC- 10011301013	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Livedo reticularis (n/a - Recovered/Resolved -)	ini amusculai j		
EU-EC- 10011301019	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Chest discomfort (2d - Recovered/Resolved			
										- Other Medically Important Condition),			
										Left ventricular hypertrophy (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011301022	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (20min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Palpitations (20min - Recovered/Resolved -)			
EU-EC- 10011301040	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR

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										Condition), Heart rate increased	n/a - Intramuscular])		
EU-EC- 10011301047	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(n/a - Unknown -) Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10011301051	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011301052	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Overdose (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Viral myocarditis (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
EU-EC-	18/01/2022	Spontaneous		Non	Not	12-17	Not	Female	No	Hospitalisation) Angiopathy (n/a -	TOZINAMERAN	[PROPRANOLOL,	ICSR
10011301265			Healthcare Professional	European Economic Area	available	Years	Specified			Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	PROPRANOLOL HYDROCHLORIDE] (C - Cardiac murmur - n/a - [n/a	
										Cyanosis (n/a - Unknown - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])	- n/a - n/a])	
										Eyelid disorder (n/a - Unknown - Other Medically Important Condition),			
										Heart rate abnormal (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown -),			
										Skin discolouration (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown -)			
EU-EC- 10011301292	18/01/2022	Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Blister (n/a - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
				Area						Condition aggravated (n/a - Recovered/Resolved - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Influenza (n/a - Unknown -),			
										Pemphigoid (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Post inflammatory pigmentation change (n/a - Unknown -),			
EU-EC-	18/01/2022	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Rash (n/a - Unknown -) Pyrexia (n/a - Not	TOZINAMERAN	Not reported	ICSR
10011301294			Professional		available	Years	Specified			Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		2001
EU-EC- 10011301319	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Hypomenorrhoea (n/a - Recovering/Resolving -),			
										Menstrual disorder (n/a -			

	1	I	I	I	ı	ı	I		 	Recovering/Resolving	I	I	ı
EU-EC-	18/01/2022	Spontaneous		European	Not	12-17	Not	Female	No	-) Balance disorder (0d	COMIRNATY	Not reported	ICSR
10011301409			Professional	Economic Area	available	Years	Specified			Recovered/Resolved -), Chills (1d - Recovered/Resolved -), Gait disturbance (0d	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Recovered/Resolved -), Pallor (0d -			
										Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved			
										Syncope (0d - Recovered/Resolved			
										Unresponsive to stimuli (1min - Recovered/Resolved -),			
										Vomiting (0d - Recovered/Resolved -)			
EU-EC- 10011301534	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (12h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
	10/01/1000					10.17				Epistaxis (12h - Recovered/Resolved -)	applicable - [n/a - n/a - n/a])		1000
EU-EC- 10011301610	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU EC	10/01/2022	Constant	New	Non	Note	12.17	Net	Note	N-	Drug ineffective (n/a - Unknown - Other Medically Important Condition)		National	TOOD
EU-EC- 10011301624	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Dry skin (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	<u>ICSR</u>
										Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	.,,		
										Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Rash erythematous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011301711	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	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	ICSR
EU-EC- 10011301750	18/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adult	Male	No	Epilepsy (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011301871	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Unknown -), Lethargy (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	19/01/2022	Sporton	Non	Non	Not	12.17	Not	Fomala	No	Syncope (n/a - Unknown - Other Medically Important Condition)		TELLIQUETING SULLOVETING	ICCD
10011301912		Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Coagulopathy (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a -	ICSR

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			Professional	Economic Area						Contusion (n/a - Recovering/Resolving -),	- COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	n/a - [n/a - n/a - n/a])	
										Haemorrhage (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving			
EU-EC- 10011301916	18/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Amnesia (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>
				Area						Asthenia (n/a - Unknown -), Dyskinesia (n/a -	immunisation - Not applicable - [1d - n/a - n/a])		
										Unknown -), Dyspnoea (n/a -			
										Unknown -), Eye movement disorder (n/a - Unknown -),			
										Hypoaesthesia (n/a - Unknown -),			
										Seizure (n/a - Unknown - Other Medically Important Condition),			
										Urinary incontinence (n/a - Unknown -)			
EU-EC- 10011301965	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (6130min - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Blood creatine phosphokinase increased (6130min - Recovered/Resolved - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Chest discomfort (5d			
										- Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Decreased activity (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Electrocardiogram ST segment elevation (6130min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Malaise (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Myopericarditis (112h - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Troponin T increased			

J.11.2022 I	1.20							IXUII L	IIIE LI	sung Report			
										(6130min - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011301974	18/01/2022	Spontaneous	Healthcare Professional	Non 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 - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011301975	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (1h - Recovered/Resolved - Other Medically Important Condition), Dizziness (1h -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition),	Intramuscular])		
										Nausea (1h - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011301976	18/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011302367	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011302462	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular])	Not reported	ICSR
										Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011302636	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011302799	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (3wk - Recovered/Resolved -), Palpitations (3wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011302875	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Blood pressure decreased (n/a - Unknown -), Immunisation reaction (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
EU-EC- 10011302879	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Unknown -) Influenza like illness (n/a - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011302880	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	C-reactive protein increased (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Gastrointestinal disorder (n/a - Recovering/Resolving -),	1{DF} - Intramuscular])		
										Weight decreased (n/a - Recovering/Resolving -)			
EU-EC- 10011302925	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovering/Resolving), Heavy menstrual	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -	Not reported	ICSR
	10/0:17					15				bleeding (n/a - Recovering/Resolving -)	Intramuscular])		
EU-EC- 10011303124	18/01/2022	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

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					Economic Area						Medically Important Condition),	immunisation - Not applicable - [1d -			
											Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])			
											Asthenia (n/a - Unknown - Other Medically Important Condition),				
											Cardiac disorder (n/a - Unknown - Other Medically Important Condition),				
											Cold sweat (n/a - Unknown - Other Medically Important Condition),				
											Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				
											Dizziness (n/a - Unknown - Other Medically Important Condition),				
											Illness (n/a - Unknown - Other Medically Important Condition),				
											Insomnia (n/a - Unknown - Other Medically Important Condition),				
											Malaise (n/a - Unknown - Other Medically Important Condition),				
											Muscular weakness (n/a - Unknown - Other Medically Important Condition),				
											Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				
											Pain in extremity (1d				
											Recovered/Resolved Other Medically Important Condition),				
											Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				
											Pain in extremity (n/a - Unknown - Other Medically Important Condition),				
											Pallor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),				
											Pallor (n/a - Unknown - Other Medically Important Condition),				
											Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition),				
	ELLEC	19/04/2022	Sports	Non	Euros	Not	10.47	Not	Eo1	N.c.	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIDNATY	Not reported	ICCS	
	EU-EC- 10011303168	18/01/2022	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>	
			au/analyti	, , , , , , ,							Headache (n/a - Not Recovered/Not	applicable - [n/a - 1{DF} - n/a])		20/7	

										Resolved -),			
										Pyrexia (n/a - Not Recovered/Not			
EU-EC- 10011303556	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Resolved -) Dizziness (20min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSF
				Area						Syncope (3min - Recovered/Resolved - Other Medically	immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC-	10/01/2022	Spontaneous	Lloolthaneo	Non	Not	12-17	Not	Male	No	Important Condition) COVID-19 (n/a -	COMIRNATY	Not reported	TCCI
0011303563	16/01/2022	Spontaneous	Professional		available	Years	Specified	Маје	NO	Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSI
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),	applicable - [1d - n/a - Intramuscular])		
										Dyspnoea (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),			
										Guillain-Barre syndrome (n/a - Unknown - Other Medically Important Condition),			
										Paralysis (n/a - Unknown - Other Medically Important Condition),			
										Pneumonia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011303586	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSF
	18/01/2022	Spontaneous		Non	Not	12-17	Not	Female	No	Fatigue (n/a -	Intramuscular]) COMIRNATY	SODIUM HYDROGEN	ICSI
10011303589			Healthcare Professional	European Economic Area	available	Years	Specified			Unknown -), Feeling cold (n/a - Unknown -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - n/a])	
										Generalised tonic- clonic seizure (0d - Recovered/Resolved - Other Medically Important Condition),	iya iyajy	[ind ind indi]	
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown -)			
EU-EC- 10011303602	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	immunisation - Not applicable - [1d -	Not reported	ICSR
										Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	n/a - Unknown])		
										Myositis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Sinus arrhythmia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Swelling (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-	10/01/2022	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Malaise (n/a -	COMIRNATY	Not reported	ICSR

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										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	n/a - Intramuscular])		
EU-EC- 10011303850	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10011303885	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (2d - Recovered/Resolved -),			
										Headache (2d - Recovered/Resolved -),			
										Nausea (2d - Recovered/Resolved -)			
EU-EC- 10011303895	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -), Blood bilirubin	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										increased (n/a - Unknown -),	applicable - [1d - n/a - n/a])		
										Hepatitis (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown -),			
										Yellow skin (n/a - Unknown -)			
EU-EC- 10011303955	18/01/2022	Spontaneous	Non Healthcare 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 -	Not reported	ICSR
										Fatigue (n/a - Unknown - Other Medically Important Condition),	n/a - n/a])		
										Myocarditis mycotic			
										Recovered/Resolved - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Syncope (n/a - Unknown - Other Medically Important Condition),			
										Tachycardia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011303986	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	Not reported	ICSR
										Influenza like illness (n/a - Not Recovered/Not Resolved -),	- [n/a - n/a - n/a])		
										Injection site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011304341	18/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Cyanosis (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
				Economic Area						Dyspnoea (n/a - Unknown -),	- COVID-19 immunisation - Not applicable - [1d -		
										Extensive swelling of vaccinated limb (n/a - Fatal - Results in Death),	n/a - Intramuscular])		
										Oedema (n/a - Unknown -)			
EU-EC- 10011304502	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

											applicable - [1d - n/a - n/a])		
U-EC- 0011304563	18/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICS
U-EC- 0011304666	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	[PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C -	ICS
				Area						Cyanosis (n/a - Unknown - Other Medically Important Condition),	immunisation - Not applicable - [n/a - n/a - n/a])	Cardiac murmur - n/a - [n/a - n/a - n/a])	
										Eyelid disorder (n/a - Unknown - Other Medically Important Condition),			
										Haematoma (n/a - Unknown - Other Medically Important Condition),			
										Heart rate abnormal (n/a - Unknown - Other Medically Important Condition),			
										Syncope (n/a - Unknown - Other Medically Important Condition),			
										Vaccination site pain (n/a - Unknown -),			
										Vasodilatation (n/a - Unknown - Other Medically Important Condition)			
I-EC- 011304671	18/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>I</u> 0
				Alea						Important Condition),	applicable - [1d - .3mL - Intramuscular])		
										Cardiac discomfort (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Discomfort (n/a - Recovering/Resolving - Other Medically Important Condition)			
-EC- 011304679	18/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	Ī
										Back pain (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Dyspnoea (3d - Recovered/Resolved - Disabling, Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Infection (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Muscular weakness (n/a - Not Recovered/Not			

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										Resolved - Disabling, Other Medically Important Condition),			
										Pain (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Paraesthesia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition),			
										Somnolence (n/a - Unknown - Disabling, Other Medically Important Condition),			
										Vitamin D decreased (n/a - Unknown - Disabling, Other Medically Important Condition)			
EU-EC- 10011305319	18/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Haematuria (n/a -	withdrawn - [1d - n/a -	Not reported	ICSR
EU-EC- 10011305485	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (5d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011305606	18/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angina pectoris (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[RISPERIDONE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - 1mg - n/a]), [RISPERIDONE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - 2mg - n/a])	<u>ICSR</u>
EU-EC- 10011306290	18/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Fatigue (n/a - Unknown -),	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 -),			
										Injection site pain (n/a - Not Recovered/Not Resolved -),			
										Injection site pruritus (n/a - Not Recovered/Not Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Recovering/Resolving -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
EU-EC-	17/01/2022	Spontaneous		Non	Not	12-17	Not	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -) C-reactive protein	COMIRNATY	Not reported	<u>ICSR</u>
10011281985			Professional	European Economic Area	available	Years	Specified			increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Chest pain (n/a - Recovered/Resolved - Caused/Prolonged			

٥	1.11.2022 1	1.23							Rull Li	IE LIS	ung Report			
											Hospitalisation), N-terminal prohormone brain natriuretic peptide increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important			
											Condition), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged			
-	EU-EC-	17/01/2022	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Hospitalisation) Blood pressure	COMIRNATY	Not reported	ICSR
	10011281989	,,		Professional	European Economic Area			Specified			decreased (n/a - Recovered/Resolved -),	[TOZINAMERAN] (S - COVID-19 immunisation - Not		
					Aicu						Cold sweat (n/a - Recovered/Resolved -),	applicable - [1d - n/a - Intramuscular])		
											Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
											Feeling abnormal (n/a - Recovered/Resolved -),			
											Feeling cold (n/a - Recovered/Resolved -),			
											Heart rate decreased (n/a - Recovered/Resolved -),			
											Hyperhidrosis (n/a - Recovered/Resolved -),			
											Muscular weakness (n/a - Recovered/Resolved -),			
											Presyncope (n/a - Recovered/Resolved -)			
	EU-EC- 10011282011	17/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
											Hyperhidrosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	n/a - n/a])		
											Inappropriate schedule of product administration (n/a - Unknown -),			
											Loss of consciousness (n/a - Unknown - Other Medically Important Condition),			
											Pallor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
	511.5G	47/0: 25-5					10:-				Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	201/201/201		
	EU-EC- 10011282358	1//01/2022	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Blindness (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>ICSR</u>

30.1	1.2022 1	1.23							IXUII LII	IE LIS	ung Report			
					Economic Area						Condition), Deafness (n/a - Unknown - Other Medically Important Condition),	immunisation - Not applicable - [1d - n/a - n/a])		
											Dizziness (n/a - Not Recovered/Not Resolved -),			
											Eye movement disorder (n/a - Not Recovered/Not Resolved -),			
											Hyperhidrosis (n/a - Not Recovered/Not Resolved -),			
											Nasopharyngitis (n/a - Unknown -),			
											Pallor (n/a - Unknown -),			
											Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
	-EC- 011282723	17/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Pyrexia (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
											Vaccination site pain (2d - Recovered/Resolved -)	applicable - [1d - .3/mL - Intramuscular])		
	-EC- 011283003	17/01/2022	Spontaneous	Non Healthcare Professional	European	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
											Chest pain (1d - Recovered/Resolved - Other Medically Important Condition),	applicable - [n/a - n/a - n/a])		
											Fatigue (n/a - Unknown - Other Medically Important Condition),			
											Lymph node pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Vaccination site warmth (n/a - Unknown - Other Medically Important Condition),			
											Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
	-EC- 011283025	17/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Child	Male	No	Abnormal behaviour (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
											Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
											Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			

										Confusional state (n/a - Not Recovered/Not Resolved -			
				I						Caused/Prolonged Hospitalisation),			
										Decreased appetite (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),			
										Heart rate irregular (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Heart rate variability increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Insomnia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pallor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										SARS-CoV-2 test negative (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011283082	17/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male		Coccydynia (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
										Syncope (n/a - Recovered/Resolved -)			
EU-EC- 10011283108	17/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Anxiety (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
										Heart rate increased (n/a - Recovered/Resolved -),	n/a - n/a])		
										Malaise (n/a - Recovered/Resolved -),			
						1	I			l	I	I	1
										Oropharyngeal pain (n/a - Recovered/Resolved -),			

0.11.2022 1	7.23							Run Li	ne Lis	ting Report			
EU-EC- 10011283195	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Lymphadenopathy (n/a - Recovering/Resolving		HUMIRA [ADALIMUMAB] (C - Juvenile idiopathic arthritis - n/a - [n/a - n/a - n/a]),	<u>ICSR</u>
										-), Myalgia (n/a - Recovering/Resolving -),	n/a - n/a])	METHOTREXATE [METHOTREXATE] (C - Juvenile idiopathic arthritis - n/a - [n/a - n/a - Oral])	
										Pain (n/a - Recovering/Resolving -),			
										Vaccination site pain (n/a - Recovering/Resolving -)			
EU-EC- 10011283237	17/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Dizziness postural (1d - Recovered/Resolved - Other Medically Important Condition),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011283277	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown -)	COMIRNATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011283430	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Unknown -)	INCOMIRATY COVID- 19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011284048	17/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asymptomatic COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation)	.,,a ca.cj		
EU-EC- 10011284110	17/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Malaise (n/a - Recovered/Resolved - Other Medically Important Condition),	n/a - n/a])		
										Pain in extremity (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011284604	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011284643	17/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Recovered/Not Resolved -) Pyrexia (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
EU-EC- 10011284648	17/01/2022	Spontaneous	Professional	Area European Economic	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (1d - Recovered/Resolved	- Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
EU-EC-	17/01/2022	Spontaneous	Professional Non	Area European	Not	12-17	Adolescent	Male	No	-) Rash (50d -	- Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY	Not reported	ICSR
10011284676		·	Healthcare Professional	Economic Area	available	Years				Recovering/Resolving -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011284848	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										•	•	•	

										Dizziness (n/a -	immunisation - Not		
		1								Unknown -),	applicable - [n/a - 1{DF} -		
										Hyperventilation (n/a - Unknown -),			
										Nausea (n/a - Unknown -),			
										Palpitations (n/a - Unknown -),			
										Panic attack (n/a - Unknown -),			
										Seizure (n/a - Unknown -),			
										Sleep disorder (n/a - Unknown -)			
EU-EC- 10011285163	17/01/2022	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Blindness transient (0d -	COMIRNATY [TOZINAMERAN] (S	Not reported	<u>ICSR</u>
			Professional	Area						Recovered/Resolved - Other Medically Important Condition),	- n/a - n/a - [n/a - n/a - n/a])		
										Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Ear discomfort (0d - Recovered/Resolved - Other Medically Important Condition),			
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011285285	17/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Swelling face (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011285645	17/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
										Chest pain (2mo - Recovered/Resolved -),	immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Dizziness (2mo - Recovered/Resolved -),			
										Heavy menstrual bleeding (2mo - Recovered/Resolved -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Nausea (2mo - Recovered/Resolved			
EU-EC- 10011285658	17/01/2022	Spontaneous	Healthcare		Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a	[TOZINAMERAN] (S	Not reported	ICSR
			Professional	VICO						Recovering/Resolving -),	immunisation - Not applicable - [n/a -		
										Heavy menstrual bleeding (n/a - Recovering/Resolving -),	1{DF} - n/a])		
										Menstruation delayed (2mo - Recovered/Resolved			
EU-EC-	17/01/2022	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Abdominal pain (n/a	COMIRNATY	Not reported	ICSR

0.11.2022 1	1.23							rull Ll	ie Lis	ung Report			
10011285686			Healthcare Professional	Economic Area	available	Years				- Not Recovered/Not Resolved -), Cold sweat (n/a - Not Recovered/Not Resolved -), Dysmenorrhoea (n/a - Not Recovered/Not Resolved -),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])		
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										bleeding (n/a - Not Recovered/Not Resolved -), Mood swings (n/a - Not Recovered/Not			
EU-EC- 10011285714	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Resolved -) Fatigue (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
										Nasopharyngitis (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not	n/a - n/a])		
										Recovered/Not Resolved -)			
EU-EC- 10011285757	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	Confusional state (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S	Not reported	<u>ICSR</u>
			Fiolessional	Alea						Life Threatening), Cyanosis (n/a - Unknown - Life Threatening),	- n/a - n/a - [1d - n/a - n/a])		
										Fatigue (n/a - Unknown - Life Threatening),			
										Loss of consciousness (n/a - Unknown - Life Threatening),			
										Pain in extremity (n/a - Unknown - Life Threatening),			
										Seizure (n/a - Unknown - Life Threatening)			
EU-EC- 10011286280	17/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 immunisation (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
										Pyrexia (n/a - Unknown -),			
										Scratch (n/a - Unknown -),			
										Syncope (n/a - Unknown -),			
	17/01/2022	Spontaneous		European	Not		Not	Male	No	Vaccination site pain (n/a - Unknown -) Chills (n/a - Not	COMIRNATY	Not reported	ICSR
10011286359			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
										Resolved -), Injection site 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 -), Pyrexia (n/a - Not Recovered/Not			
1		Spontaneous		European	Not	12-17	Adolescent		No	Resolved -) Herpes zoster (n/a -	COMIRNATY	Not reported	ICSR

0.11.2022 1	1.23							Run Li	ne Lis	sting Report			
EU-EC- 10011286427	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Gingival erythema (n/a - Unknown - Disabling), Gingival swelling (n/a - Unknown - Disabling), Tonsillitis (n/a - Unknown - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011286439	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (12h - Recovered/Resolved -), Rash papular (12h - Recovered/Resolved -), Skin swelling (12h - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011286820	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Hypoaesthesia (n/a - Not Recovered/Not Resolved -), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Sensory disturbance (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011286900	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Vaccination site movement impairment (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011287032	17/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Inappropriate schedule of product administration (n/a - Unknown -), Pelvic haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaginal haemorrhage (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DESOGESTREL] (C - Adenomyosis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10011287037	17/01/2022	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), Illness (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
EU-EC- 10011287124	17/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Heavy menstrual bleeding (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
EU-EC- 10011287208	17/01/2022	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	C-reactive protein increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

3().11.2022 1	1.23							Run Lii	ne Lis	ung Report			
											Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Computerised tomogram abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Cyanosis (10h - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Cytokine storm (n/a - Fatal - Results in Death, Other Medically Important Condition),			
											Death (n/a - Fatal - Results in Death, Other Medically Important Condition),			
											Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Dyspnoea (12h - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Fatigue (12h - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Fibrin D dimer increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
											Oxygen saturation decreased (12h - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Pyrexia (12h - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition),			
											Serum ferritin increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),			
											Tachypnoea (12h - Fatal - Results in Death, Caused/Prolonged			
	EU-EC- 10011287484	17/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Not Specified	Yes	Hospitalisation) Cystatin C increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
	EU-EC- 10011287642	17/01/2022	Spontaneous	Non Healthcare		Not available	12-17 Years	Not Specified	Female	No	Vaccination site pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
	1001120/042			Professional		avaliable	rears	эрестеа			Vaccination site swelling (n/a - Unknown -), Vaccination site warmth (n/a -	imunisation - Not applicable - [1d - n/a - Intramuscular])		
	EU-EC- 10011287683	17/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Unknown -) Headache (24h - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	<u>ICSR</u>
1-4	tna://dan.ar		<i></i>		20-									F0/7/

.11.2022 1	1.23						Run Li	ne Lis	ling Report			
									Nausea (24h - Recovered/Resolved -),	applicable - [n/a - n/a - n/a])		
									Pyrexia (24h - Recovered/Resolved -),			
									Vomiting (24h - Recovered/Resolved			
EU-EC- 10011287808	17/01/2022	Spontaneous	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	Not reported	ICSR
									Pyrexia (n/a - Not Recovered/Not Resolved - Disabling)	applicable - [n/a - n/a - n/a])		
EU-EC- 10011287826	17/01/2022	Spontaneous	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Muscle spasms (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Ill-defined disorder - n/a - [n/a - n/a - n/a]),	ICSR
									Muscle spasms (n/a - Unknown -),	n/a - Parenteral])	[PARACETAMOL] (C - III- defined disorder - n/a - [n/a - n/a - n/a])	
									Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC- 10011287831	17/01/2022	Spontaneous	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Headache (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
									Heart rate increased (0d -	n/a - n/a])		
									Recovered/Resolved - Other Medically Important Condition),			
									Migraine without aura (0d - Recovered/Resolved - Other Medically Important Condition),			
									Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition),			
									Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011287838	17/01/2022	Spontaneous	Non European Economic Area	Not available		Not Specified	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
									Fatigue (n/a - Unknown - Other Medically Important Condition),	n/a - n/a])		
									Myocarditis (n/a - Unknown - Other Medically Important Condition),			
									Neck mass (n/a - Unknown - Other Medically Important Condition),			
									Oesophagitis (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),			
									Pyrexia (n/a - Unknown - Other Medically Important Condition),			
									Tachycardia (n/a - Unknown - Other			

										Medically Important Condition)			
EU-EC- 10011287890	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Chills (n/a - Recovering/Resolving -),			
										Dizziness (n/a - Recovering/Resolving -),			
										Dyspnoea (n/a - Unknown -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Recovering/Resolving -),			
										Malaise (n/a - Not Recovered/Not Resolved -),			
										Myalgia (n/a - Not Recovered/Not Resolved -),			
										Nausea (1d - Recovered/Resolved -),			
										Pain (n/a - Not Recovered/Not Resolved -),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved -),			
										Vaccination site pruritus (n/a - Not Recovered/Not Resolved -),			
										Vision blurred (n/a - Recovering/Resolving -)			
EU-EC- 10011287953	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (7d - Recovered/Resolved -), Menstrual disorder (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Not Resolved -), Polymenorrhoea (n/a			
EU-EC-	17/01/2022	Spontaneous	Hoalthcaro	Non	Not	12-17	Not	Male	No	- Not Recovered/Not Resolved -) COVID-19 (n/a -	COMIRNATY	Not reported	ICSR
10011288063	17/01/2022	Sportaneous	Professional		available	Years	Specified	Male	NO	Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSK
										Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011288360	17/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011288364	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
	.=					15				Tremor (0d - Recovered/Resolved -)			
EU-EC- 10011288471	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Limb discomfort (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pain (0d - Recovered/Resolved -)			
EU-EC- 10011288564	17/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10011288610		Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Male	No	Breast pain (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR

0.11.2022 1	1.23							Run L	ne Lis	sting Report			
			Professional	Area						- Caused/Prolonged Hospitalisation),	- Immunisation - n/a - [n/a - n/a - n/a])		
										Dyspnoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011288733	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (7wk - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR
										Fatigue (7wk - Recovering/Resolving -),	applicable - [1min -		
										Headache (7wk - Recovering/Resolving -),			
										Nasopharyngitis (7wk - Recovering/Resolving -),			
										Oropharyngeal pain (7wk - Recovering/Resolving -),			
										Pyrexia (7wk - Recovering/Resolving -)			
EU-EC- 10011289120	17/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Loss of consciousness (1min	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR
										Recovered/Resolved - Other Medically Important Condition)	immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
EU-EC- 10011289203	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
										Confusional state (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	1{DF} - Intramuscular])		
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011289390	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Face oedema (n/a - Unknown -), Fatigue (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
										Influenza like illness (n/a - Unknown -)	Intramuscular])		
EU-EC- 10011289406	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Parotitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10011289407	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (4d - Recovered/Resolved -),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR
										Dyspnoea (4d - Recovered/Resolved	[1d - 1{DF} - Intramuscular])		
EU-EC- 10011289413	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovering/Resolving -), Vision blurred (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	17/01/2022	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Recovering/Resolving -) Headache (n/a -	COMIRNATY	Not reported	ICSR
10011289414		SP	Healthcare Professional	Economic	available	Years				Recovering/Resolving -), Tinnitus (n/a - Recovering/Resolving	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} -		
										-), Vertigo (n/a - Recovering/Resolving			
EU-EC- 10011289429	17/01/2022	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	-) Oedema peripheral (2d - Unknown -),	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
				Area						Rash pruritic (2d - Unknown -)	- COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])		
EU-EC- 10011289558	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (1d - Recovered/Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

0.11.2022 1	7.20							r turr Er		aling Report			
										Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),	1{DF} - Intramuscular])		
										Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011289655	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (2d - Recovering/Resolving -), Immunisation reaction (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011289690	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011289705	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011289707	17/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Loss of consciousness (1d - Recovered/Resolved -), Myoclonus (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011289713	17/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovering/Resolving -), Malaise (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011289753	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011289777	17/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition aggravated (n/a - Not Recovered/Not Resolved -), Thrombocytopenia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [34d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011289806	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (6d - Recovered/Resolved -), Rash pruritic (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011289815	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tachycardia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10011289875	17/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (5wk - Not Recovered/Not Resolved -)	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011289905	17/01/2022	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} - Intramuscular])	Not reported	ICSR
EU-EC- 10011290003	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

0.11.2022 1								· tuii Li		sting report			
										Recovered/Not Resolved -)	immunisation - n/a - [n/a - n/a -		
EU-EC- 10011290295	17/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	Intramuscular]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
EU-EC-	17/01/2022	Chantanagus	Healtheave	Europoon	Not	12.17	Adolescent	Fomalo	No	Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIDNATY	Not reported	ICCD
10011290468	17/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	remale	No	discomfort (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Headache (n/a - Unknown - Other Medically Important Condition),			
										Iron deficiency (n/a - Unknown - Other Medically Important Condition),			
										Transferrin saturation (n/a - Unknown - Other Medically Important Condition),			
										Urinary tract infection (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011291272	17/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Clostridium difficile infection (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	PROBIOTICS NOS [PROBIOTICS NOS] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMINS NOS] (C - n/a -	ICSR
										Gastrointestinal haemorrhage (n/a - Unknown - Other Medically Important Condition),	n/a - Intramuscular])	n/a - [n/a - n/a - n/a])	
										Rectal haemorrhage (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011291380	17/01/2022	Spontaneous	Healthcare	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 - [1d -	Not reported	ICSR
										Ear swelling (n/a - Unknown - Other Medically Important Condition), Erythema (n/a -	n/a - n/a])		
										Unknown - Other Medically Important Condition),			
										(4d - Recovered/Resolved - Other Medically Important Condition),			
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (7d - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition),			

0.11.2022 1	1.23							Run Li	ne Lis	ung Report			
										Swelling face (n/a - Unknown - Other Medically Important Condition),			
										Tearfulness (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011291389	17/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Colitis ulcerative (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	[TOZINAMERAN] (S	Not reported	ICSR
										Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Haematochezia (n/a			
										Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011292039	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (9d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	<u>ICSR</u>
										Menstruation irregular (9d - Recovered/Resolved -)	1{DF} - n/a])		
EU-EC- 10011292415	17/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011292473	17/01/2022	Spontaneous	Non 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	Not reported	<u>ICSR</u>
										Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	applicable - [n/a - 1{DF} - n/a])		
										Recovered/Not Resolved -), Injection site			
										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 -),			
EU-EC-	16/01/2022	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -) COVID-19 (n/a -	COMIRNATY	Not reported	ICSR
10011280581	20,01,2022	Spontaneous	Professional		available	Years	AUGSCEIL	riule	140	Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	not reported	<u>1CJR</u>
EU EO	10.10.15.	Const	1112	.	Not	42.1=			NI.	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMPLICATION		105-
EU-EC-	16/01/2022	Spontaneous	Healthcare	European	Not	12-17	Adolescent	remale	No	COVID-19 (n/a -	COMIRNATY	Not reported	<u>ICSR</u>

0.11.2022 1	1.23							IXUII LI	HE LIS	sung Report			
10011280687			Professional	Economic Area	available	Years				Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -		
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)	Intramuscular])		
EU-EC- 10011280718	16/01/2022	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- 10011280726	16/01/2022	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- 10011280744	16/01/2022	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	<u>ICSR</u>
EU-EC-	16/01/2022	Spontaneous	Hoalthcaro	European	Not	12-17	Adolescent	Eomala	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a -	COMIRNATY	Not reported	ICSR
10011280748	10/01/2022	Spontaneous		Economic Area	available	Years	Adolescent	Terriale	INO	Unknown - Other Medically Important Condition),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSK
	16 (01 (000)					10.17				Vaccination failure (n/a - Unknown - Other Medically Important Condition)			1000
EU-EC- 10011280815	16/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	remale	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011280824	16/01/2022	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	<u>ICSR</u>
EU-EC-	16/01/2022	Chantanagua	Llogith care	Furancan	Not	12.17	Adolescent	Mala	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a -	COMPNIATY	Not reported	TCCD
10011280840	10/01/2022	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Маје	No	Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
FILEC	16/01/2022	Constant	I I a a lith an ii a	F	Niet	12.17	Adalasant	FI-	NI-	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMPONATY	Naharanda	ICCD
EU-EC- 10011280926	16/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	remale	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
EU-EC-	16/01/2022	Sportaneous	Hoolthoore	Europoon	Not	12.17	Adolescent	Mala	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a -	COMIDNATY	Not reported	ICCD
10011280929	16/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Мане	No	Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
FILES	16 (01 (2022	Constant	I I III	5	Niet	12.17	Adalasasat	Mala	NI-	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMPONATY		Tech
EU-EC- 10011280933	10/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	ı™ale	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
EU-EC-	16/01/2022	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY	Not reported	ICSR
10011280953	10/01/2022	эропанеоиѕ		Economic Area	available	Years	Specified	n ciliale	INU	consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	not reported	ICSK
										Seizure (n/a - Unknown - Caused/Prolonged			

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March Marc									Syncope (n/a - Unknown - Caused/Prolonged			
1-3		16/01/2022	Spontaneous	Healthcare	Economic		Male	No	Arthralgia (n/a - Recovering/Resolving -), Chills (n/a -	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR
Public P									-), Fatigue (n/a - Not Recovered/Not	1{0F} - 11/4])		
EU-EC- 10011261105 Bell-2022 Sportaneous Month Professional Professional Sportaneous Month Professional Month Professional Sportaneous Month Professional Month Professional Sportaneous Month Professional Mo									Headache (n/a - Recovering/Resolving			
ELEC. 16/01/2022 Spontaneous Mon-healthcare European Professional Area Professional									Recovered/Not Resolved -),			
EU-EC- 10011281195 15/01/2022 Spontaneous In Professional Scromer Profes									Recovered/Not Resolved -), Pyrexia (n/a - Not			
Recovered (Resolve - - - - - - - - -		16/01/2022	Spontaneous	Healthcare	Economic		Male	No	Resolved -) Fatigue (n/a - Not Recovered/Not	[TOZINAMERAN] (S - COVID-19	Not reported	ICSR
EU-EC- 10011281136 EU-EC- 10011281136 EU-EC- 10011281281									Recovered/Resolved	applicable - [n/a -		
EU-EC- 10011281356 EU-EC- 1011281356 EU-EC- 1011281356 EU-EC- 1011281357 EU-EC- 1011281357 EU-EC- 1011281358 EU-EC- 10112									haematoma (2d - Recovered/Resolved			
EU-EC- 16/01/2022 Spontaneous Healthcare European Professional Area European Not available Area Not available Area Not available N									inflammation (2d - Recovered/Resolved			
EU-EC- 10011281149 EU-EC-									(2d - Recovered/Resolved			
EU-EC- 10011281136 EU-EC- 10011281136 EU-EC- 10011281149 EU-EC-									(2d - Recovered/Resolved			
EU-EC- 10011281136 EU-EC- 10011281136 EU-EC- 10011281137 EU-EC- 10011281137 EU-EC- 10011281138 EU-Policia Recovering/Resolving -									Recovering/Resolving -),			
Professional Economic Area available Vears Specified Unknown - Caused/Prolonged Hospitalisation), Feeling cold (n/a Unknown - Caused/Prolonged Hospitalisation), Pericarditts (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericarditts (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericarditts (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Troponin increased									Recovering/Resolving			
EU-EC- 10011281149 Individual companies of the professional of		16/01/2022	Spontaneous		Economic		Male	No	Unknown - Caused/Prolonged	[TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL -	Not reported	ICSR
EU-EC- 10011281149 EU-EC- 10011281149 EU-FC-									Unknown - Caused/Prolonged			
EU-EC- 10011281149 EU-EC- 10011281149 EU-FC- 10011281149									(n/a - Unknown - Caused/Prolonged			
EU-EC- 10011281149 EU-EC- 1001128149 EU-EC- 1001128149 EU-EC- 1001128149 EU-EC- 1001128149 E									Unknown - Caused/Prolonged			
EU-EC- 10011281149 Comparison Compariso									Unknown - Caused/Prolonged			
10011281149 Professional Economic Area available Years Specified Unknown - [TOZINAMERAN] (S - n/a - n/a - [n/a - [n/a - n/a - [n/a -									(n/a - Unknown - Caused/Prolonged Hospitalisation)			
		16/01/2022	Spontaneous		Economic		Male	No	Unknown - Caused/Prolonged	[TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
EU-EC- 10011281161 Spontaneous Healthcare Professional Feanuric Area Healthcare Professional Feanuric Area Not available Vears Specified Specif		16/01/2022	Spontaneous		Economic		Male	No	Unknown - Caused/Prolonged	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSR

										Unknown - Caused/Prolonged			
EU-EC- 10011281169	16/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hospitalisation) Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICS
										Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011281237	16/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic shock (n/a - Unknown - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	IC
										Confusional state (n/a - Unknown - Life Threatening),	Intramuscular])		
										Hypotonia (n/a - Unknown - Life Threatening), Hypotonic-			
										hyporesponsive episode (n/a - Unknown - Life Threatening)			
EU-EC- 10011281258	16/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	<u>IC</u>
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Heart rate increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011281450	16/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	<u>IC</u>
EU-EC- 10011277829	15/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	IC
EU-EC- 10011278120	15/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-) Headache (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	<u>IC</u>
										Malaise (1d - Recovered/Resolved -),	immunisation - n/a - [n/a3mL - Intramuscular])		
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10011278475	15/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>IC</u>
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vertigo (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-		Spontaneous	1		Not	12-17	Not	Female	No	+	COMIRNATY	Not reported	IC 50

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10011278498			Healthcare Professional		available	Years	Specified			Not Recovered/Not Resolved -), Balance disorder (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not			
										Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011279970	15/01/2022	Spontaneous		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	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011280020	15/01/2022	Spontaneous		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	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011280240	15/01/2022	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	<u>ICSR</u>
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011262438	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011262623	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										-), Pain in extremity (n/a - Recovered/Resolved -),			
EU-EC-	14/01/2022	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Pyrexia (n/a - Recovered/Resolved -) Pericarditis (26d -	COMIRNATY	Not reported	ICSR
10011262957		·		Economic Area	available	Years	Specified			Recovered/Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	·	
EU-EC- 10011263563	14/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Heavy menstrual bleeding (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Inappropriate schedule of product administration (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011263598	14/01/2022	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Lymphadenopathy			

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REFC 1401/2022 Spartnesses Nathers 1500 National Nat											Recovered/Not			
March Perfect Perfec											Lymphangitis (n/a - Not Recovered/Not Resolved - Other Medically Important			
BLESC MAD MAD Made M		14/01/2022	Spontaneous		Economic				Male	No	(0d - Recovered/Resolved	[TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR
Execution at		14/01/2022	Spontaneous	Healthcare	Economic			Adolescent	Male	No		COMIRNATY [TOZINAMERAN] (S	Not reported	<u>ICSR</u>
14-01/2022 Sportamonal Section											reaction (n/a -	- [n/a - n/a - n/a])		
Supplication Processing Process Proces	EU EC	44/04/2022	Constant	New	-	N	12.17	A.I.I.	F	N.	Unknown -)	COMPRIATY	Networked	TOOD
EU-EC- 14/01/2022 Spontaneous Most Preference Most P		14/01/2022	Spontaneous	Healthcare	Economic			Adolescent	Female	No	(n/a - Recovered/Resolved	[TOZINAMERAN] (S - Immunisation - n/a	Not reported	ICSR
101126448 Professional Recognition R														
European New European New European New Professional Aroa Professional Pr		14/01/2022	Spontaneous		Economic				Male	No	(n/a - Recovering/Resolving	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
Recovered/Not. Recove		14/01/2022	Spontaneous	Healthcare	Economic				Female	No	Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a -	Not reported	ICSR
Recovered/Not Resolver - 1, Recovered/Not Recovered/No											Recovered/Not			
EU-EC- 14/01/2022 Spontaneous Non Healthcare European Not 12-17 Not Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination Recovered/Not Resolved -), Vaccination site hyperselective of the pain Recovered/Not Resolved -), Vaccination Resolved -), Vaccination Recovered/Not											Recovered/Not			
Becovered/Not Resolved - J. Hydigia (fr/a - Not Recovered/Not Resolved - J.) Pyresia (fr/a - Not Recovered/Not Resolved - J.) Pyresia (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Recovered/Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccination site Input (fr/a - Not Resolved - J.) Vaccinati											(n/a - Not Recovered/Not			
Recovered/Not Resolved 1.) Pyrread (n/a - Not Recovered/Not Resolved 1.) Pyrread (n/a - Not Recovered/Not Resolved 1.) Vaccination site pain (n/a - Not Recovered/Not Resolved 1.) Vaccination site pain (n/a - Not Recovered/Not Resolved 1.) Vaccination site pain (n/a - Not Recovered/Not Resolved 1.) Vaccination site pain (n/a - Not Recovered/Not Resolved 1.) Vaccination site pain (n/a - Not Recovered/Not Resolved 1.) Vaccination site pain (n/a - Not Recovered/Not Resolved 1.) Vaccination site pain (n/a - Not Recovered/Not Resolved 1.) Vaccination site pain (n/a - Not Recovered/Not Resolved 1.) Vaccination site pain (n/a - Not Recovered/Not Resolved 1.) Vaccination site pain (n/a - Recovering/Resolving 1.) Complete (n/a - Not Recovering/Resolving 1.) Introduction (n/a - n/a - n/a) Recovering/Resolving 1. Introduction (n/a - n/a - n/a) Vaccination site pain (n/a - n/a - n/a) Vaccination site pain (n/a - Recovering/Resolving 1.) Introduction (n/a - Not Recovering/Reso											Recovered/Not			
Recovered/Not Resolved -). Vaccination site hypersensitivity (nfa hypersensity (nfa hypersensity (nfa hypers											Recovered/Not			
EU-EC- 10011264460 EU-EC- 10011264460 EU-FEC- 10011264460 EU-FEC- 10011264460 EU-FEC- 10011264460 EU-FEC- 10011264460 EU-FEC- 10011264460 EU-FEC- 10011264460 Impairment (na - Not Recovered/Not Resolved -), Vaccination site movement impairment (na - Not Recovered/Not Resolved -), Vaccination site pair (na - Not Recovered/Not Resolved -), Vaccination site pair (na - Not Resolved											Recovered/Not			
EU-EC- 10011264460 EU-EC- 10011264460 EU-EC- 10011264460 EU-EC- 10011264460 EU-EC- 10011264460 EU-EC- Professional Area Not Recovered/Not Recovered/No											hypersensitivity (n/a - Not Recovered/Not			
EU-EC- 10011264460 It/01/2022 Spontaneous Professional Spontaneous Professional Specified Speci											movement impairment (n/a - Not Recovered/Not			
EU-EC- 10011264460 In the part of the par											(n/a - Not Recovered/Not			
- Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination site pain		14/01/2022	Spontaneous	Healthcare	Economic				Female	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important	[TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported	ICSR
- Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination site pain											-			
Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination site pain											- Other Medically Important			
Recovering/Resolving - Other Medically Important Condition), Vaccination site pain											Recovering/Resolving - Other Medically Important			
											Recovering/Resolving - Other Medically Important			

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											Recovering/Resolving - Other Medically Important Condition),			
											Visual impairment			
											(n/a - Recovering/Resolving			
											- Other Medically Important Condition)			
		14/01/2022	Spontaneous		European	Not		Not	Female	No	Asthenia (n/a -	COMIRNATY	Not reported	<u>ICSR</u>
	10011264463			Healthcare Professional	Economic Area	available	Years	Specified			Recovered/Resolved With Sequelae -	[TOZINAMERAN] (S - COVID-19		
					/ 54						Caused/Prolonged Hospitalisation),	prophylaxis - n/a - [n/a - n/a -		
											' "	Intramuscular])		
											Diabetic ketoacidosis (n/a -			
											Recovered/Resolved With Sequelae -			
											Caused/Prolonged Hospitalisation),			
											Dry mouth (n/a -			
											Recovered/Resolved With Sequelae -			
											Caused/Prolonged			
											Hospitalisation),			
											Fatigue (n/a - Recovered/Resolved			
											With Sequelae - Caused/Prolonged			
											Hospitalisation),			
											Hypoglycaemia (n/a			
											- Recovered/Resolved			
											With Sequelae - Caused/Prolonged			
											Hospitalisation),			
											Pollakiuria (n/a -			
											Recovered/Resolved With Sequelae -			
											Caused/Prolonged Hospitalisation),			
											Somnolence (n/a -			
											Recovered/Resolved With Sequelae -			
											Caused/Prolonged			
											Hospitalisation),			
											Thirst (n/a - Recovered/Resolved			
											With Sequelae - Caused/Prolonged			
											Hospitalisation),			
											Type 1 diabetes			
											mellitus (n/a - Recovered/Resolved			
											With Sequelae - Caused/Prolonged			
											Hospitalisation),			
											Visual impairment (n/a -			
											Recovered/Resolved			
											With Sequelae - Caused/Prolonged			
											Hospitalisation),			
											Weight decreased (n/a -			
											Recovered/Resolved With Sequelae -			
											Caused/Prolonged Hospitalisation)			
		14/01/2022	Spontaneous		European	Not		Not	Male	No	Facial bones fracture	COMIRNATY	Not reported	ICSR
	10011264464			Professional	Economic Area	available	Years	Specified			(n/a - Recovering/Resolving	[TOZINAMERAN] (S - COVID-19		
											- Caused/Prolonged Hospitalisation),	immunisation - n/a - [n/a - n/a -		
											Fall (n/a -	Intramuscular])		
											Recovering/Resolving			
											- Caused/Prolonged Hospitalisation),			
											Loss of			
											consciousness (n/a - Recovering/Resolving			
											- Caused/Prolonged Hospitalisation),			
											Skin injury (n/a -			
											Recovering/Resolving			
											- Caused/Prolonged Hospitalisation),			
											Tooth injury (n/a -			
											Recovering/Resolving - Caused/Prolonged			
	ELLEC	14/01/2022	Cnontant	Non	Europa	Not	12.17	Not	Com-1-	Ne	Hospitalisation) Asthenia (1mo - Not	COMIDNATY	Not reported	ICCD
	EU-EC- 10011264465	14/01/2022	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Recovered/Not	COMIRNATY [TOZINAMERAN] (S	Not reported	<u>ICSR</u>
				Professional	Area						Resolved -),	- n/a - n/a - [n/a -		

0.11.2022 1	7.20							IXUII LI	HE LIS	ung Report			
										Body temperature increased (1mo - Not Recovered/Not Resolved -), Dysphonia (1mo - Not Recovered/Not Resolved -),	n/a - Intramuscular])		
										Oropharyngeal pain (1mo - Not Recovered/Not Resolved -),			
										Rhinorrhoea (1mo - Not Recovered/Not Resolved -)			
EU-EC- 10011264466	14/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -),	- COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
										Vaccination site pain (n/a - Recovering/Resolving -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC- 10011264480	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Discomfort (n/a - Recovering/Resolving -),	- n/a - n/a - [n/a - n/a -	Not reported	ICSR
										Injection site erythema (n/a - Recovering/Resolving -),	Intramuscular])		
										Injection site movement impairment (n/a - Recovering/Resolving -),			
										Loss of personal independence in daily activities (n/a - Recovering/Resolving -),			
										Lymph node pain (n/a - Recovering/Resolving -),			
										Lymphadenopathy (n/a - Recovering/Resolving -),			
										Pain in extremity (n/a - Recovering/Resolving -)			
EU-EC- 10011264482	14/01/2022	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Blood pressure abnormal (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Heart rate abnormal (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vaccination site discomfort (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011264530	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011264679	14/01/2022	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving	COMIRNATY	Not reported	ICSR

0.11.2022 1								· (aii Li		ting report			
			Professional	Economic Area						- Other Medically Important Condition),	- COVID-19 immunisation - Not applicable - [1d -		
										Dyspnoea (13d - Recovered/Resolved - Other Medically Important Condition),	n/a - n/a])		
										Inappropriate schedule of product administration (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- 10011264964	14/01/2022	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a -	Not reported	ICSR
											Intramuscular])		
EU-EC- 10011265006	14/01/2022	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (n/a - Unknown -), Local reaction (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a -	Not reported	<u>ICSR</u>
		_								Unknown -)	Intramuscular])		
EU-EC- 10011265051	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Dizziness (0d - Recovered/Resolved -),			
										Headache (0d - Recovered/Resolved -),			
										Malaise (0d - Recovered/Resolved -),			
										Nausea (0d - Recovered/Resolved -),			
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10011265071	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area		12-17 Years	Adolescent	Male	No	Chills (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (0d - Recovered/Resolved -)			
EU-EC- 10011265083	14/01/2022	Spontaneous	Non Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Fatigue (n/a - Not Recovered/Not Resolved -),	[:,,a :,,a :,,a])		
										Hyperhidrosis (n/a - Not Recovered/Not Resolved -),			
										Influenza (n/a - Not Recovered/Not Resolved -),			
										Limb discomfort (n/a - Not Recovered/Not Resolved -),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Paraesthesia (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Vomiting (n/a - Recovering/Resolving -)			
EU-EC-	14/01/2022	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Chest pain (n/a -	COMIRNATY	Not reported	ICSR

0.11.2022 1	1.23							Kull Li	He LIS	ting Report			
10011265120			Healthcare Professional		available	Years				Recovering/Resolving - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
										Chills (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011265127	14/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Not Specified	No	Headache (2d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
10011203127			Professional		available	rears		эрестеч		-), Injection site pain (2d -	- Immunisation - n/a - [n/a - n/a - n/a])		
										Recovering/Resolving			
										Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10011265748	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ANTICONCEPTIEPIL [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC- 10011265820	14/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (3mo -	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
10011203020			Professional		available	rears				Recovered/Resolved - Disabling)	- COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
EU-EC- 10011265928	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cerebral haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL -	Not reported	ICSR
										Concussion (n/a - Unknown - Caused/Prolonged Hospitalisation),	Intramuscular])		
										Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Loss of consciousness (n/a - Unknown - Caused/Prolonged			
										Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011266094	14/01/2022	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Bronchitis (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
				Area		·				Chest discomfort (n/a - Not Recovered/Not Resolved -),	- COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Chest pain (n/a - Recovering/Resolving -),			
										Costochondritis (n/a - Unknown -),			
										Dyspnoea (n/a - Not Recovered/Not Resolved -),			
										Lower respiratory tract infection (n/a - Unknown -),			
										Pain (n/a - Unknown -),			
EU-EC-	14/01/2022	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Tenderness (n/a - Unknown -) Aphasia (6d -	COMIRNATY	Not reported	ICSR
10011266130			Professional	Economic Area	available	Years				Recovered/Resolved - Caused/Prolonged Hospitalisation),	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -		

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											Recovered/Resolved - Caused/Prolonged			
Processed Searchest											Recovered/Resolved - Caused/Prolonged			
Processed Received Process											Recovered/Resolved - Caused/Prolonged			
1947 1947											Recovered/Resolved - Caused/Prolonged			
14-07-2022 Sportsonessis Norm Companies Norm Companies Norm Companies Norm Companies Norm											(6d - Recovered/Resolved - Caused/Prolonged			
Professional Prof	EU-EC-	14/01/2022	Spontaneous	Non	European	Not	12-17	Not	Female	No		COMIRNATY	Not reported	ICSR
Passage Pass	10011266308		·			available	Years	Specified			-), Fatigue (n/a -	- COVID-19 immunisation - Not applicable - [n/a -		
BL-EC											Recovering/Resolving -),	1{DF} - n/a])		
EU-EC- 14/01/2022 Spontaneous Healthcase European Not 12-17 Addescent Male Not Recovering/Resolved 1-10 Not Recovering/Resolved											Recovered/Resolved -),			
Recovered (Rescheed - 1, Nausa (24 - Recovered											(n/a - Recovered/Resolved			
ELFEC 14/01/2022 Sportnaneous Healthcare European Not 21-17 Adolescent Male No Erphrena melitification Country (COVID-Not reported 10/1266431 14/01/2022 Sportnaneous Not											Recovered/Resolved			
EU-EC- 10011266431 14/01/2022 Spontaneous Healthcare European Professional Economic Area European Professional Economic Professional Formation Spontaneous Healthcare European Professional Economic Profess											Recovered/Resolved			
EU-EC- 10/01/2022 Spontaneous Realthcare Professional 2											Recovered/Resolved			
Professional Economic Area Ar											Recovering/Resolving			
EU-EC- 10011266622 14/01/2022 Spontaneous Nome Healthcare Economic Professional Real Real Real Real Real Recovering Resolved Recovering Resolved Recovering Resolved Recovering Resolving Resolving Resolving Resolving Recovering Resolving Recovering Resolving Resolving Resolving Resolving Recovering Resolving Resolving Resolving Resolving Recovering Resolving Recovering Resolving Resolving Recovering Resolving Recovering Resolving Resolving Resolving Resolving Recovering Resolving Recovering Resolving Resolving Recovering Resolving Recovering Resolving Recovered/Resolved Recovered	EU-EC- 10011266431	14/01/2022	Spontaneous		Economic			Adolescent	Male	No	(8d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically	19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a 3ml		ICSR
Fatigue (8d - Recovering/Resolving -), Headache (3d - Recovering/Resolving -), Pyrexia (1d - Recovering/Resolving -), Py	EU-EC- 10011266622	14/01/2022	Spontaneous	Healthcare	Economic			Adolescent	Male	No	Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S		ICSR
EU-EC- 10011266648 EU-EC- 100112666719 EU-EC- 100112666719 EU-EC- 100112666719 EU-EC- 100112666719 EU-EC- 10011266719 Not reported European Not European Not Healthcare Professional European Not European Not Healthcare Professional European Not European Not Recovered/Resolved -) European Not European Not Recovered/Resolved -) Fatigue (2d - Recovered/Resolving -) Feeling hot (0d - Recovered/Resolved -) Feeling hot (0d - Recovered/Resolved -) Headache (2d - Recovered/Resolved -)											Fatigue (8d - Recovering/Resolving	- [n/a - n/a - n/a])		
EU-EC- 10011266648 14/01/2022 Spontaneous											Recovered/Resolved			
EU-EC- 1001126648 14/01/2022 Spontaneous Non Healthcare Professional Area Spontaneous Non Healthcare Professional Non Healthcare Professional Professional Non Healthcare Professional Professional Non											Recovering/Resolving			
EU-EC-10011266719 14/01/2022 Spontaneous Non Healthcare Professional Available Spontaneous Non Healthcare Professional Adolescent Nol Recovered/Resolved Spontaneous Non Healthcare Professional No	EU-EC- 10011266648	14/01/2022	Spontaneous	Healthcare	Economic			Adolescent	Male	No	Influenza (0d - Unknown -), Oropharyngeal pain	[TOZINAMERAN] (S - Immunisation - n/a		ICSR
Dizziness (0d - Recovered/Resolved -), Fatigue (2d - Recovering/Resolving -), Feeling hot (0d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -),	EU-EC- 10011266719	14/01/2022	Spontaneous	Healthcare	Economic			Adolescent	Male	No	Chills (2d - Recovered/Resolved	[TOZINAMERAN] (S	· .	ICSR
Fatigue (2d - Recovering/Resolving -), Feeling hot (0d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -),											Dizziness (0d - Recovered/Resolved			
Feeling hot (0d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -),											Fatigue (2d - Recovering/Resolving			
Recovered/Resolved -),											Feeling hot (0d - Recovered/Resolved			
											Recovered/Resolved			
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0.11.2022 1	1.23							Kull L	ille Lis	sting Report			
										Injection site pain (1d - Recovering/Resolving -), Pyrexia (0d - Recovered/Resolved			
EU-EC- 10011266737	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	-) Chills (0d - Recovered/Resolved -), Myalgia (1d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Pyrexia (0d - Not Recovered/Not Resolved -)			
EU-EC- 10011266752	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	маю	No	Feeling hot (0d - Unknown -), Pyrexia (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011266809	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011266814	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Paraesthesia (n/a - Recovering/Resolving -), Sensory level abnormal (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving			
EU-EC- 10011266819	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Not Resolved -)			
EU-EC- 10011266832	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza (3d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011266839	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Troponin increased (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011266845	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
										Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Troponin increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011267028	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011267033	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011267575	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (7d - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011267827	14/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Heart rate irregular (n/a - Recovering/Resolving	(COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

0.11.2022 1										ting report			
										- Other Medically Important Condition),			
										Lymphadenopathy			
										(n/a - Recovering/Resolving - Other Medically Important			
										Condition), Myocarditis (n/a - Unknown - Other Medically Important			
										Condition), Nausea (2d - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (2d			
										Recovered/Resolved Other Medically Important Condition),			
										Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pericarditis (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011267849	14/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	syndrome (1d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
										Peripheral swelling (1d - Recovered/Resolved - Other Medically Important Condition),			
										Swelling (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011267851	14/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	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
										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011267878	14/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Insomnia (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
										Seizure (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011267921	14/01/2022	Spontaneous		European Economic	Not available		Not Specified	Female	No	Blister (n/a - Not	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR

0.11.2022 1	1.23							Rull Li	ne Lis	ung Report			
			Professional	Area						Resolved -), Oral mucosal blistering (n/a - Not Recovered/Not Resolved -), Oropharyngeal blistering (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tongue blistering (n/a - Not	- COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Recovered/Not Resolved -)			
EU-EC- 10011268130	14/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Myalgia (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011268406	14/01/2022	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 -), Menstruation delayed (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011268414	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthritis (n/a - Recovering/Resolving - Other Medically Important Condition)	- Immunisation - n/a	Not reported	ICSR
EU-EC- 10011269026	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deep vein thrombosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
EU-EC- 10011269097	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	Not reported	ICSR
EU-EC- 10011269163	14/01/2022	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Male	No	Vomiting (0d - Recovered/Resolved -)	- [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011269167	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10011269168	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10011269474	14/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a -	Not reported	ICSR
EU-EC- 10011269659	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Infection (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011269776	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Herpes zoster (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011269788	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -	Not reported	ICSR
EU-EC- 10011269825	14/01/2022	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not	Intramuscular]) COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR

J.11.2022 I	1.23							Rull L	ille Li	sung Report			
			Professional	Area						Recovered/Not Resolved -)	- COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC- 10011270078	14/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea (n/a - Unknown -),			
										Rash (n/a - Unknown			
EU-EC- 10011270331	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011270518	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Multisystem inflammatory syndrome in children (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10011270600	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Encephalitis autoimmune (7d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011271411	14/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase increased (n/a - Unknown -), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
EU-EC-	14/01/2022	Spontaneous	Lloolthanus	Non	Not	12-17	Not	Female	No	Troponin T increased (n/a - Unknown -) Dizziness (84min -	COMIRNATY	Not reported	ICSR
10011271427	14/01/2022	Sportarieous	Professional	European Economic Area	available	Years	Specified	remale	NO	Recovered/Resolved -), Syncope (4min - Recovered/Resolved - Other Medically	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSP
EU-EC- 10011272208	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Head injury (n/a - Unknown - Other Medically Important Condition),	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a3mL -	Not reported	ICSR
										Hypotonic- hyporesponsive episode (n/a - Unknown - Other Medically Important Condition),	Intramuscular])		
EU EO	14/0:15					10.7				Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	COMPLUTE (
EU-EC- 10011272773	14/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011274532	14/01/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a	Intramuscular]) COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR
			Professional							Recovering/Resolving			

).11.2022 1	1.23							Run Li	ne Lis	sting Report			
										Heavy menstrual bleeding (n/a - Recovering/Resolving	- Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011275515	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	-) Influenza like illness (1wk - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011275543	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	-) COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011275979	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Important Condition) Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving	- COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
FILE 60	4.4/04/2022					12.17		14-1-	N.	Pyrexia (n/a - Recovering/Resolving -)			1000
EU-EC- 10011275990	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	маlе	No	Dizziness (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -),	- COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10011276009	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dermatitis allergic (n/a - Recovered/Resolved -), Dyspnoea (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Myalgia (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSE
										Vomiting (3d - Recovered/Resolved -)			
EU-EC- 10011276040	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011276095	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (2d - Recovering/Resolving -)	COMIRNATY	Not reported	ICSR
EU-EC- 10011276232	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011276237	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Unknown -), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011276243	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (2d - Recovered/Resolved -), Vaccination site pain (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011276282	14/01/2022	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	-) Urticaria (22d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S	Not reported	ICSR

1.11.2022 1	1.23							Rull L	HE LIS	sung Report			
				Area						- Other Medically Important Condition)	- COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])		
EU-EC- 10011276294	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011276304	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved -), 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- 10011276335	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF}} - n/a - More in ICSR])	Not reported	ICSR
EU-EC- 10011276347	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site erythema (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011276363	14/01/2022	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011276545	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site swelling (0d - Recovered/Resolved -), Limb discomfort (1d - Recovered/Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011276999	14/01/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011277140	14/01/2022	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- 10011277141	14/01/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011277366	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011277642	14/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (4d - Not Recovered/Not Resolved -), Urticaria (4d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011277672	14/01/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Apnea (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

30.11.2022 1	1.23							Kuli Li	He LIS	ung Report			
										Unknown - Other Medically Important Condition),			
										Seizure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011245944	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a	Not reported	ICSR
										Dizziness (0d - Recovered/Resolved -),	- [n/a - n/a - n/a])		
										Headache (0d - Recovered/Resolved -),			
										Injection site pain (1d - Recovered/Resolved -)			
EU-EC- 10011245955	13/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011245959	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Influenza (1d - Recovered/Resolved -),	- [II/a - II/a - II/a])		
										Nausea (1d - Not Recovered/Not Resolved -)			
EU-EC- 10011245983	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (1d - Recovered/Resolved -),			
										Injection site pain (1d - Recovered/Resolved -)			
EU-EC- 10011246037	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011246064	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Injection site pain (2d - Recovered/Resolved -),	[1,44 1,44 1,44])		
										Malaise (4d - Recovered/Resolved -)			
EU-EC- 10011246069	13/01/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (1d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Fatigue (0d - Recovered/Resolved -),			
										Headache (0d - Recovered/Resolved -),			
										Influenza (1d - Recovering/Resolving -),			
EU-EC-	13/01/2022	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Limb discomfort (0d - Not Recovered/Not Resolved -) Chills (0d -	COMIRNATY	Not reported	ICSR
10011246128			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved -), Injection site pain	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	·	
										(2d - Recovered/Resolved -),			
EU-EC-	13/01/2022	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Vomiting (0d - Recovered/Resolved -) Influenza (1d - Not	COMIRNATY	Not reported	ICSR
10011246145		·	Healthcare Professional	Economic Area	available	Years				Recovered/Not Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011246175	13/01/2022	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Paraesthesia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	13/01/2022	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Influenza (n/a - Not	COMIRNATY	Not reported	<u>ICSR</u>

Run Line Listing Report

10011246200	100	lealthcare rofessional	available	Years		Recovered/Not Resolved -)	[TOZINAMERAN] (S - Immunisation - n/a		
							- [n/a - n/a - n/a])		Ĺ

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