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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary 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)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC- 10011099092	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011099166	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Not Resolved -)			
EU-EC- 10011099380	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Troponin increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011099482	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011099603	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Recovered/Resolved -), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10011099651	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Unknown -), Headache (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Lethargy (n/a - Unknown -),			
										Pyrexia (n/a - Unknown -), Syncope (n/a -			
										Unknown - Other Medically Important Condition)			
EU-EC- 10011099744	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Alopecia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099745	28/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099751	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011099752	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099753		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Abdominal pain upper (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		ICSR
EU-EC- 10011099755	28/12/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC-	28/12/2021	Spontaneous	Professional Non		Not available	12-17	Adolescent	Male	No	Influenza like illness	- n/a - n/a]) COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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10011099758			Healthcare Professional			Years				(1d - Recovered/Resolved	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011099760	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Migraine (40d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099761	28/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (56d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099763	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Appendicitis (5d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099766	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (23d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099768	28/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (193d - Recovered/Resolved -), Headache (193d - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (193d - Unknown -)			
EU-EC- 10011099771	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (0d - Recovered/Resolved With Seguelae -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099772	28/12/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (2d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099773	28/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Muscle twitching (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011099775	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Paraesthesia (23d - Unknown -), Swelling (23d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099778	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (109d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099779	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (12d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Palpitations (12d - Recovered/Resolved -)			
EU-EC- 10011099780	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Neurodermatitis (107d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011099785	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099789	28/12/2021	Spontaneous	Non	European Economic	Not available	12-17 Years	Adolescent	Female	No	Pruritus (n/a -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011099796	28/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Eye swelling (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
EU-EC- 10011099800	28/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011099820	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Injection site pain (2d - Recovered/Resolved -)			
EU-EC- 10011099823	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Inflammation (23d - Recovered/Resolved -), Influenza (6d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Injection site pain (23d -			
EU-EC-	28/12/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Female	No	Recovering/Resolving -) Abdominal pain	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011099828	,,,,,,,,,			Economic		Years				upper (n/a - Recovered/Resolved -),	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Headache (n/a - Recovered/Resolved -),			
										Visual impairment (n/a - Recovered/Resolved -)			
EU-EC- 10011099846	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),			

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										Injection site pain (4d - Recovered/Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -),			
										Tremor (n/a - Not Recovered/Not Resolved -),			
										Visual impairment (n/a - Not Recovered/Not			
EU-EC-	28/12/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Resolved -) Fatigue (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011099865		·		Economic Area		Years				Recovered/Not Resolved -), Feeling hot (n/a -	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Not Recovered/Not Resolved -),			
										Gastrointestinal pain (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Injection site erythema (n/a - Not Recovered/Not			
										Resolved -), Injection site pain (n/a - Not			
										Recovered/Not Resolved -), Injection site			
										swelling (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011099879	28/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Pain in extremity (n/a - Unknown -), Pyrexia (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved			
EU-EC- 10011099894	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICSR
										Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011099911		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Asthenia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	·	ICSR
EU-EC- 10011099939	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	remale	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	[TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	<u>ICSR</u>
										Vaccination failure (n/a - Recovering/Resolving - Other Medically			
EU-EC-	20/12/2021	Casatanasus	Non	Furancan	Net evelleble	12 17	Adolescent	Mala	No	Important Condition) COVID-19 (n/a -	COMIDMATY [TOTIMAMEDAN]	COMIRNATY	ICCD
10011099982	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	ман	NO	Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	[TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	<u>ICSR</u>
										Vaccination failure (n/a - Recovering/Resolving - Other Medically			
EU-EC- 10011100101	28/12/2021	Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Blood pressure decreased (n/a - Recovered/Resolved	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
				Area						Loss of consciousness (n/a -	n/a])		
										Recovered/Resolved - Other Medically Important Condition),			
										Pallor (n/a - Recovered/Resolved -),			
EU-EC-	20/42/2021	Coorter	Non	Non	Not available	12.17	Not	Mal-	Ne	Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN]	Not rope to	ICCD
10011100119	20/12/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Male	No	Behaviour disorder (n/a - Not Recovered/Not	(S - COVID-19 immunisation -	постеропеа	<u>ICSR</u>

				Economic Area						Resolved - Caused/Prolonged Hospitalisation,	Not applicable - [n/a - n/a - n/a])		
										Disabling), Disturbance in attention (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Facial discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Facial spasm (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Mental status changes (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Muscle twitching (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),			
										Repetitive speech (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation,			
										Disabling), Soliloquy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)			
EU-EC-	28/12/2021	Spontaneous						-					<u>ICSR</u>
10011100130		Spontaneous	Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Petechiae (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	I COIX
EU-EC- 10011100417	28/12/2021	Spontaneous	Professional	European Economic Area Non	Not available			Female	No	Unknown - Other Medically Important Condition) Chest pain (n/a - Not Recovered/Not	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported Not reported	ICSR
EU-EC-	28/12/2021		Professional Healthcare	European Economic Area Non European		Years	Specified Not			Unknown - Other Medically Important Condition) Chest pain (n/a - Not	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN]		
EU-EC-	28/12/2021		Professional Healthcare	European Economic Area Non European Economic		Years	Specified Not			Unknown - Other Medically Important Condition) Chest pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
EU-EC-	28/12/2021		Professional Healthcare	European Economic Area Non European Economic		Years	Specified Not			Unknown - Other Medically Important Condition) Chest pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
EU-EC-	28/12/2021		Professional Healthcare	European Economic Area Non European Economic		Years	Specified Not			Unknown - Other Medically Important Condition) Chest pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
EU-EC-	28/12/2021		Professional Healthcare	European Economic Area Non European Economic		Years	Specified Not			Unknown - Other Medically Important Condition) Chest pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Heypertension (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
EU-EC-	28/12/2021		Professional Healthcare	European Economic Area Non European Economic		Years	Specified Not			Unknown - Other Medically Important Condition) Chest pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hypertension (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
EU-EC-	28/12/2021		Professional Healthcare	European Economic Area Non European Economic		Years	Specified Not			Unknown - Other Medically Important Condition) Chest pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hypertension (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
EU-EC-	28/12/2021		Professional Healthcare	European Economic Area Non European Economic		Years	Specified Not			Unknown - Other Medically Important Condition) Chest pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hypertension (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
EU-EC-	28/12/2021		Professional Healthcare	European Economic Area Non European Economic		Years	Specified Not		No	Unknown - Other Medically Important Condition) Chest pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hypertension (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
EU-EC-	28/12/2021		Professional Healthcare	European Economic Area Non European Economic		Years	Specified Not		No	Unknown - Other Medically Important Condition) Chest pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hypertension (n/a - Not Recovered/Not Resolved -), Hypertension (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (n/a - Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -		
EU-EC-			Professional Healthcare Professional	European Economic Area Non European Economic Area European Economic Economic Economic Economic European Economic		Years	Specified Not	Female	No	Unknown - Other Medically Important Condition) Chest pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hypertension (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Not Resolved -), Vaccination site swelling (n/a - Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	

			Professional	Area						Recovered/Not Resolved -)	- n/a - n/a])		
EU-EC- 10011100756	28/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Recovering/Resolving -), Back pain (3d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Recovered/Resolved -), Chest pain (6d - Recovered/Resolved			
										-), Chills (1d - Recovered/Resolved			
										-), Myalgia (7d - Recovered/Resolved			
										Pyrexia (2d - Recovered/Resolved			
EU-EC- 10011100768	28/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Chills (2d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Influenza (6d - Not Recovered/Not Resolved -),			
										Injection site pain (8d - Recovering/Resolving -),			
										Menstrual disorder (11d - Not Recovered/Not Resolved -)			
EU-EC- 10011100769	28/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Chest pain (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Chills (1d - Unknown -),			
										Night sweats (1d - Recovered/Resolved -), Testicular pain (0d -			
EU-EC- 10011100773	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Unknown -) Syncope (0d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011100781	28/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Important Condition) Headache (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
			, roressione.	7.1.00						Paraesthesia (1d - Recovered/Resolved -),	.va Internasculary		
										Peripheral vascular disorder (1d - Recovered/Resolved			
EU-EC- 10011100785	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011100787	28/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011100789		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Epistaxis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	,	ICSF
EU-EC- 10011100791	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Injection site pain (2d - Recovered/Resolved -),			
										Menstrual disorder (158d - Not Recovered/Not Resolved -)			
EU-EC- 10011100793	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011100794	28/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011100796	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (0d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
										Myopericarditis (23d - Recovering/Resolving - Caused/Prolonged			
EU-EC- 10011100797	28/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Hospitalisation) Epididymitis (8d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI

EU-EC- 10011100798	28/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Swelling face (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011100799	28/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Recovered/Not Resolved -), Injection site pain			
										(n/a - Unknown -), Malaise (n/a -			
EU-EC- 100111100801	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Unknown -) Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSI
EU-EC- 10011100802	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	+	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011100803	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011100804	28/12/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Tinnitus (135d - Recovering/Resolving		Not reported	ICSF
EU-EC- 10011100805	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Cyst (9d - Recovered/Resolved	- n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011100806	28/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Male	No	Alopecia (132d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011100814	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal discomfort (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSF
										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC- 10011100817	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (0d - Recovering/Resolving -), Headache (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC-	28/12/2021	Spontaneous		European	Not available	12-17	Adolescent	Female	No	Recovering/Resolving -) Arthritis allergic (n/a	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10011100818			Healthcare Professional	Economic Area		Years				Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-	28/12/2021	Spontaneous			Not available		Adolescent	Female	No	-) Facial paralysis (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10011100819			Healthcare Professional	Economic Area		Years				Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011100822	28/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Headache (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Influenza like illness (15d - Recovered/Resolved - Caused/Prolonged			
										Hospitalisation), Paraesthesia (15d - Recovered/Resolved - Caused/Prolonged			
EU-EC- 10011100824	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hospitalisation) Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011100832	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSF
										Hypoaesthesia eye (n/a - Recovered/Resolved			
EU-EC- 10011100838	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10011100890	28/12/2021	Spontaneous	Non	European Economic	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
										Thrombocytopenia (3d - Recovered/Resolved - Caused/Prolonged			
EU-EC- 10011100901	28/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSF
		1	1	1	I .					Restlessness (n/a -			1

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10011100906			Healthcare Professional			Years				(n/a - Not Recovered/Not Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC- 10011100910	28/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Influenza (1d - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	29/12/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Fomalo	No	Hospitalisation) Dyspnoea (15d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011100913	20/12/2021	Sportaneous		Economic	NOL available	Years	Adolescent	remale	INO	Unknown -), Menstrual disorder	(S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC-	28/12/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	(6d - Unknown -) Cough (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011100916			Healthcare Professional	Economic Area		Years				Recovered/Not Resolved -), Dysphonia (n/a - Not	(S - Immunisation - n/a - [n/a - n/a - n/a])		
										Recovered/Not Resolved -)			
EU-EC- 10011100970	28/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
										Injury (n/a - Unknown - Other Medically Important	Intramuscular])		
										Condition), Pruritus (n/a - Unknown - Other Medically Important			
										Condition), Urticaria (n/a - Unknown - Other			
										Medically Important Condition)			
EU-EC- 10011077676	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Contusion (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
										Headache (n/a - Recovering/Resolving -),	Intramuscular])		
										Injection site pain (n/a - Recovering/Resolving			
										Malaise (n/a - Recovering/Resolving			
										Pyrexia (n/a - Recovering/Resolving -),			
										Somnolence (n/a - Recovering/Resolving			
EU-EC- 10011077728	27/12/2021	Spontaneous	Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				Area						Gait disturbance (n/a - Unknown -),	n/a])		
										Helplessness (n/a - Unknown -),			
										Hyperventilation (n/a - Not Recovered/Not Resolved -),			
										Initial insomnia (n/a - Unknown -), Malaise (n/a -			
										Unknown -), Neurological symptom (n/a -			
										Unknown -), Suicide attempt (n/a - Unknown - Other			
EU-EC-	27/12/2021	Spontaneous		Non	Not available	12-17	Not	Female	No	Medically Important Condition) Autonomic nervous	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011078208				European Economic Area		Years	Specified			system imbalance (n/a - Unknown - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
										Blood pressure decreased (n/a - Unknown - Other Medically Important			
										Condition), Ear discomfort (n/a - Recovered/Resolved - Other Medically			
										Important Condition), Gait disturbance (n/a			
										- Unknown -),			
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										Heart rate decreased (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Unknown -),			
										Vision blurred (n/a - Unknown - Other Medically Important Condition),			
										Visual impairment (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011078305		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (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
										Troponin increased (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011078317	27/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (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
										Illness (6d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011078344	27/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Myocarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
				71100						Not Recovered/Not Resolved - Other Medically Important Condition)	1,141)		
EU-EC- 10011078472	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	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>
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011078478		Spontaneous	Healthcare Professional	Non European Economic Area	Potts, E Was it COVID19 or the vaccine a rare case of SARS-COV2 infection or post-vaccine triggered flare in juvenile dermatomyositis	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Unknown - Other Medically Important Condition), Dermatomyositis (n/a - Unknown -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
					Pediatric Rheumatology. 2021;19(SUPPL 1):135-136. doi:10.1186/s12969- 021-00632-z					Other Medically Important Condition)			
EU-EC- 10011078495		Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Hypotension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Hypotonia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Stridor (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011078525	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	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	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011078538		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	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	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011078551	27/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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										Condition), Drug ineffective (n/a	Not applicable - [n/a - n/a - n/a])		
										- Unknown - Other Medically Important Condition)			
EU-EC- 10011078555	27/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Not Recovered/Not Resolved -),			
										Herpes simplex (n/a - Unknown -),			
										Lip pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling),			
										Muscle twitching (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling)			
EU-EC- 10011078586	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
				, , , ,						Headache (n/a - Not Recovered/Not Resolved -),	.,,=1)		
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011078618	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
										Vaccination site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011078668	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Lymph node pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011078746	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Unknown -)			
EU-EC- 10011079015	27/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Arthralgia (n/a - Unknown -),			
										Myalgia (n/a - Unknown -),			
										Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
EU-EC-	27/12/2021	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Vaccination site pain (n/a - Unknown -) Dizziness (2d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
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10011079471			Healthcare Professional	European Economic Area		Years	Specified			Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Medically Important Condition), Illness (n/a - Recovering/Resolving - Other Medically Important			
										Condition), Myalgia (2d - Recovered/Resolved - Other Medically Important Condition),			
										Photophobia (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011079544	27/12/2021	Spontaneous	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 - [1d - n/a - Intramuscular])	Not reported	ICSR
										Cold sweat (0d - Recovered/Resolved -), Hyperhidrosis (0d -			
EU-EC- 10011079652	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved -) Arthralgia (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	[TOPIRAMATE] (C - Migraine - n/a - [n/a - n/a - n/a])	ICSR
				Area						Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	n/a])		
EU-EC- 10011079930		Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Guttate psoriasis (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011079933	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition) Dysmenorrhoea (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011079974	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]	Not reported	ICSR
										Dizziness (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a -	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Unknown - Other Medically Important Condition),			
										hyporesponsive episode (n/a - Unknown - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important Condition),			
										Seizure (n/a - Unknown - Other Medically Important Condition),			
EU-EC-	27/12/2021	Spontaneous	Healthcare	European	Not available	12-17	Not	Male	No	Somnolence (n/a - Unknown - Other Medically Important Condition)	COMIRNATY CONCENTRATE	Not reported	ICSR
10011080155			Professional			Years	Specified			Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a -	FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL -	·	
										Unknown - Caused/Prolonged Hospitalisation),	Intramuscular])		
T	I	I	I	I	I	I	I	I	I	(n/a - Unknown -	I	I	1 1

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										Caused/Prolonged Hospitalisation),			
										Monoparesis (n/a - Unknown - Caused/Prolonged			
										Hospitalisation), Transient ischaemic attack (n/a - Unknown -			
EU-EC-	27/12/2021	Chantanagus	Hoaltheare	European	Not available	12-17	Not	Male	No	Caused/Prolonged Hospitalisation) Diarrhoea (n/a -	COMIDNATY CONCENTRATE	Not reported	ICCD
10011080216		Spontaneous	Professional		Not available	Years	Specified	Маје	NO	Unknown - Other Medically Important Condition),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]	Not reported	<u>ICSR</u>
										Hypotonic- hyporesponsive episode (n/a - Unknown - Other Medically Important Condition),	(S - n/a - n/a - [n/a3mL - Intramuscular])		
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Syncope (n/a - Unknown - Other Medically Important Condition),			
						10.17				Vomiting (n/a - Unknown - Other Medically Important Condition)			1000
EU-EC- 10011080264	2//12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
										Erythema (n/a - Recovering/Resolving -), Headache (n/a -			
										Recovering/Resolving -), Malaise (n/a - Not			
										Recovered/Not Resolved -), Paraesthesia oral			
										(n/a - Recovering/Resolving -)			
EU-EC- 10011080367	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Migraine (n/a - Recovering/Resolving -), Migraine (n/a -			
										Unknown -), Nausea (n/a - Recovering/Resolving			
EU-EC- 10011080563	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Face injury (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICSR
										Hospitalisation), Syncope (n/a - Recovered/Resolved With Sequelae -	MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC- 10011080659	27/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Caused/Prolonged Hospitalisation) Facial paralysis (n/a - Recovered/Resolved	COMIRNATY CONCENTRATE FOR DISPERSION FOR	Not reported	ICSR
10011080039			Professional			rears	эрестеи			- Other Medically Important Condition),	INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -		
										Fatigue (n/a - Recovered/Resolved -),	Întramuscular])		
										Pain in extremity (n/a - Recovered/Resolved -),			
										Pyrexia (n/a - Recovered/Resolved -),			
EU-EC-	27/12/2021	Spontaneous	Healthcare	European	Not available	12-17	Not	Male	No	Swelling face (n/a - Recovered/Resolved - Other Medically Important Condition) Myopericarditis (2d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011080801 EU-EC-		Spontaneous	Professional		Not available	12-17 Years	Specified Not	Male	No	Myopericarditis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation) Cough (n/a - Not	(S - n/a - n/a - [n/a - n/a - n/a]) COMIRNATY CONCENTRATE	Not reported	ICSR ICSR
10011081411	27/12/2021	Sportaneous		Economic	INUL AVAIIADIE	Years	Specified	male	INO	Recovered/Not Resolved -),	FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	mot reported	ICSK

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										Productive cough (n/a - Not Recovered/Not Resolved -),	MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])		
										Pyrexia (n/a - Not Recovered/Not			
EU-EC- 10011081455	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved -) Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Net positional pages and a second content of the covider of the	Not reported	ICSR
										Dysphoria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	Not applicable - [n/a - n/a - n/a])		
										Insomnia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011081509	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-), Fatigue (n/a -	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]	Not reported	<u>ICSR</u>
										Recovering/Resolving -), Pain in extremity (n/a -	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Recovering/Resolving -), Peripheral swelling (n/a -			
									Recovering/Resolving -), Pyrexia (n/a - Not Recovered/Not				
									Resolved -), Vaccination site pain (n/a -				
	27/12/2021	Spontaneous			Not available	12-17	Not	Female	No	Recovering/Resolving -) Heavy menstrual	COMIRNATY [TOZINAMERAN]		ICSR
10011081604			Healthcare Professional	Economic Area		Years	Specified			bleeding (n/a - Recovering/Resolving -), Heavy menstrual	(S - Immunisation - n/a - [n/a - n/a - Intramuscular])	(C - n/a - n/a - [n/a - n/a - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL,	,
										bleeding (n/a - Unknown -), Menstruation irregular (n/a -		LACTOSE ANHYDROUS] (C - Contraception, Dysmenorrhoea - n/a - [n/a - n/a - Oral])	
EU-EC-	27/12/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Female	No	Recovering/Resolving -) Myalgia (n/a -	COMIRNATY [TOZINAMERAN]		ICSR
10011081849			Healthcare Professional	Economic Area		Years				Unknown -)	(S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC- 10011082269	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011083159	27/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Cough (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])	Not reported	<u>ICSR</u>
										Unknown - Other Medically Important Condition),			
									Unknown - Other Medically Important Condition), Vaccination failure				
										(n/a - Unknown - Other Medically Important Condition)			
					Not available	12-17	Not	Male	No	Chest pain (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
EU-EC- 10011083198	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Years	Specified			-), Headache (n/a -	Not applicable - [1d - n/a - n/a])		
	27/12/2021	Spontaneous		European Economic	not available	Years	Specified			-),	Not applicable - [1d - n/a -		

			I	I	l	I			1	Recovering/Resolving	1		I
EU-EC- 10011083265	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Aspartate aminotransferase increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Hospitalisation), Blood creatine phosphokinase MB increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Blood creatine phosphokinase increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										C-reactive protein increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011083706	27/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Female	No	Tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not reported	<u>ICS</u>
EU-EC- 10011083813	27/12/2021	Spontaneous	Healthcare Professional		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	ICS
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011083980	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10011083985	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Thrombosis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011084011	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotension (n/a - Recovered/Resolved -), Pallor (n/a - Unknown -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSF
FILES	27/42/555		llast!!	New	No.	10.45	Net	E		Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMPANY (TOTAL)	No.	7.00
EU-EC- 10011084017 EU-EC-		Spontaneous	Professional	Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	·	ICSF
EU-EC- 10011084037		Spontaneous Spontaneous	Professional	Non European Economic Area	Not available Not available	12-17 Years	Not Specified	Female Female	No No	Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN]	·	ICSF
10011084045			Professional	European Economic Area		Years	Specified			Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC- 10011084083	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF

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										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011084103	27/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovered/Not Resolved -), Echocardiogram			
										abnormal (n/a - Not Recovered/Not Resolved -),			
										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Troponin increased (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011084198	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (2wk - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011084651	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011084691	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -),	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
										Pain in extremity (1d - Recovered/Resolved -)	n/a - [n/a3mL - Intramuscular])		
EU-EC- 10011084701	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011084836	27/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (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
										Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011084839	27/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Hyperhidrosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Malaise (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Platelet count decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011085352	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011085353	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ageusia (n/a - Not Recovered/Not Resolved -), Decreased appetite	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
ELLEC	77/47/2021	Cnorter	Non	Conservation	Not availed:	12.47	Adeles	Formal	N-	(n/a - Not Recovered/Not Resolved -)	COMIDNATY ITOZINAMED	FICOTOFTINO N. C.	Toos
EU-EC- 10011085392		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Pigmentation disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Acne - n/a - [n/a - n/a - n/a])	
EU-EC- 10011085423	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

EU-EC- 10011085451	27/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovering/Resolving -), Insomnia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	AERIUS 5 MG FILM- COATED TABLET [DESLORATADINE] (C - Antiallergic therapy - Unknown - [n/a - n/a - n/a])	ICS
EU-EC- 10011085468	27/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011085469	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011085572	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-), Allergy to vaccine	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										(n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Henoch-Schonlein			
										purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Illness (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not			
										Recovered/Not Resolved -), Rash papular (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation), Renal impairment (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011085577	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (1d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10011085585	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (1h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011085731	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011085902	27/12/2021	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Myocarditis (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICS
				Area			·			- Caused/Prolonged Hospitalisation)	- n/a - n/a])		
EU-EC- 10011085913		Spontaneous	Professional	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])	·	ICS
EU-EC- 10011085921		Spontaneous	Professional	Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	·	ICS
EU-EC- 10011085922	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10011085986	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011086241	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Cardio-respiratory arrest (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICS
										Shock (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			

	10.13									Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged			
EU-EC- 10011086270	27/12/2021	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	ICS
										Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011086317	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure diastolic decreased (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	IC
										Fall (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Head injury (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Heart rate decreased (0d - Recovered/Resolved - Other Medically Important Condition),			
										Hyperventilation (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										PO2 increased (0d - Recovered/Resolved - Other Medically Important Condition)			
:U-EC- 0011086474	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination failure (19d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d3mL -	Not reported	<u>I</u>
:U-EC- 0011086479	27/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyskinesia (0d - Recovered/Resolved - Other Medically Important Condition),	Intramuscular J) TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	L
										Gaze palsy (0d - Recovered/Resolved - Other Medically Important Condition),			
	27/12/222					12.12				Pallor (0d - Recovered/Resolved -)			
U-EC- 0011086722	27/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	10
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
U-EC- 0011086839	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyskinesia (n/a - Recovering/Resolving -), Hypoaesthesia (n/a -		[RISPERIDONE] (C - Schizophrenia - n/a - [n/a - n/a - Oral])	I
										Recovering/Resolving -), Injury (n/a -			
										Unknown -), Mobility decreased			
										(n/a - Recovering/Resolving -), Movement disorder			
										(n/a - Recovering/Resolving -),			
										Muscular weakness (n/a - Recovering/Resolving -),			
		 a.eu/ana								" Neuropathy			1

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										peripheral (39417min - Recovered/Resolved - Other Medically Important Condition),			
										Tremor (n/a - Recovering/Resolving -),			
										Vaccination site irritation (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011086886		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- 10011086925	2//12/2021	Spontaneous	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
EU EC	27/12/2021	Spontaneous	I I a likh a a sa	5	Not available	12.17	A delegant	Famala	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIDNATY (TOTALAMEDAN)	Note was auto-d	ICCD
EU-EC- 10011086934	27/12/2021	Sportalieous	Professional		Not available	12-17 Years	Adolescent	remale	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011087290		Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No		COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10011087320		Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Spinal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011087467	27/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Application site pain (2d - Recovered/Resolved -), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved -), Headache (1d - Recovered/Resolved -),			
										Pyrexia (1d - Recovered/Resolved -)			
EU-EC- 10011087786		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Asthenia (n/a - Recovered/Resolved -),			
										Ligament sprain (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -),			
										Rash (n/a - Recovered/Resolved -)			
EU-EC- 10011088251	27/12/2021	Spontaneous	Healthcare Professional		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
					<u></u>					Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011088260		Spontaneous	Healthcare Professional		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
EU = 2	07/15 :-			-		40 :				Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMPANIE (To	No.	
EU-EC- 10011088468		Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	remale	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

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										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011088653	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
										Vomiting (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011088716	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10011088717	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Unknown -), Vaccination site inflammation (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10011088718	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 10011076869	26/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Chills (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not			
										Recovered/Not Resolved -), Nausea (n/a - Not			
EU-EC-	26/12/2021	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No	Recovered/Not Resolved -) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011077015		'	Professional			Years				Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown -	(S - n/a - n/a - [n/a - n/a - Intramuscular])	·	
EU-EC-	26/12/2021	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Other Medically Important Condition) Amenorrhoea (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011077091			Healthcare Professional	Economic Area		Years	Specified			Not Recovered/Not Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC- 10011077159	26/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Fatigue (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not			
										Resolved -), Malaise (n/a - Recovering/Resolving			
										Myalgia (3d - Recovered/Resolved			
										Nausea (n/a - Recovering/Resolving			
EU-EC- 10011077234	26/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown -), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovering/Resolving -), Malaise (n/a -	- 11/4])		
										Recovering/Resolving -), Nausea (n/a - Not			
EU-EC-	26/12/2021	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Recovered/Not Resolved -) Headache (1d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011077384		·	Healthcare Professional	Economic		Years	Specified			Recovered/Resolved -), Injection site erythema (n/a - Recovering/Resolving	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	·	
										Injection site inflammation (n/a - Recovering/Resolving			
										-),			

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										Injection site pain (n/a - Recovering/Resolving -),			
										Injection site swelling (n/a - Recovering/Resolving -),			
										Lymphadenopathy (n/a - Not Recovered/Not Resolved -),			
										Malaise (0d - Recovered/Resolved			
										Pyrexia (1d - Recovered/Resolved			
EU-EC- 10011077521	26/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent	Male	No	Vaccination failure (10d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011075291	25/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011075764	25/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Fatigue (2d - Recovered/Resolved -),			
										Headache (2d - Recovered/Resolved -),			
										Injection site erythema (n/a - Recovered/Resolved -),			
										Injection site inflammation (n/a - Recovered/Resolved -),			
										Injection site pain (n/a - Recovered/Resolved -),			
										Malaise (2d - Recovered/Resolved -),			
										Myalgia (2d - Recovered/Resolved -),			
										Nausea (12h - Recovered/Resolved -)			
EU-EC- 10011076158	25/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Influenza (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011076379	25/12/2021	Spontaneous	Healthcare Professional		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- 10011076387	25/12/2021	Spontaneous	Healthcare Professional		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- 10011076436	25/12/2021	Spontaneous	Healthcare Professional		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- 10011076542	25/12/2021	Spontaneous	Healthcare Professional		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- 10011065868	24/12/2021	Spontaneous	Non Healthcare		Not available		Not Specified	Female	No	Heart rate increased (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown	Not reported	ICSR

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		Professional	Area						Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	- [n/a3mL - Intramuscular])		
24/12/2021				Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICS
									Polymerase chain reaction (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
									Procalcitonin increased (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
									Troponin increased (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
24/12/2021		Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICS
									Headache (n/a - Unknown - Other Medically Important Condition),			
									Muscle spasms (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
									Myalgia (n/a - Unknown - Other Medically Important Condition)			
24/12/2021		Healthcare		Not available	12-17 Years	Not Specified	Female	No	Arthralgia (1d - Recovered/Resolved -), Chills (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	IC
									-), Fatigue (1d - Recovered/Resolved -),			
									Headache (1d - Recovered/Resolved -),			
									Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved			
24/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Extraocular muscle disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition).	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014,	Not reported	ICS
									Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014,		
									Off label use (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Immunisation -		
									Photophobia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	Not applicable - [1d - n/a - n/a])		
			1	I	1				Product use issue			
	24/12/2021	24/12/2021 Spontaneous 24/12/2021 Spontaneous 24/12/2021 Spontaneous	24/12/2021 Spontaneous Healthcare Professional Spontaneous Non Healthcare Professional Advice Professional Spontaneous Non Healthcare Professional Advice Professional Spontaneous Non Healthcare Professional	24/12/2021 Spontaneous Healthcare Professional European Economic Area 24/12/2021 Spontaneous Non Healthcare Professional European Economic Area 24/12/2021 Spontaneous Non Healthcare Professional Economic Area 24/12/2021 Spontaneous Non Healthcare Professional Economic Area	24/12/2021 Spontaneous Healthcare Professional Area Not available Economic Area Not available Economic Area Not available Economic Area Not available Economic Area Professional Feoreman Economic Area 24/12/2021 Spontaneous Non Healthcare Professional Area Not available Economic Area	24/12/2021 Spontaneous Professional Realthcare Professional Economic Area Not available 12-17 Years Non Healthcare Professional Economic Area Non Healthcare Professional Economic Area Not available 12-17 Years 24/12/2021 Spontaneous Non Healthcare Professional Area Non Area Non Area Not available 12-17 Years Non Area Not available 12-17 Years	24/12/2021 Spontaneous Non Healthcare Professional Reconomic Area Not available 12-17 Specified Not available 12-17 Years Specified Not available 12-17 Years Specified Not available 12-17 Specified Not available 12-17 Years Specified Reconomic Area Not available 12-17 Years Specified Not available 12-17 Specified Not available 12-17 Specified	Professional Area	24/12/2021 Spontaneous Non Healthcare Professional Area No Healthcare Professional Area Non Healthcare Pro	Professional Area Analyza Sportaneous Meditarium Desperation of Cauself Professional Cauself	2412/2021 Sourcements New Yorks and Processes New York State 2412/2021 Sourcements New York St	Professoral Processoral Processor Processoral Processoral Processor Processoral Processor Processor Processor Processoral Processor Proc

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										(n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
EU-EC-	24/12/2021	Spontaneous	Non	Non	Not available	12-17	Not	Female	No	(n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) Chills (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011067146	- 1, 12, E3E1	Sportariosas	Healthcare Professional	European		Years	Specified	, cinale		Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	The Topolited	1001
										Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving			
										- Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically			
										Important Condition), Sinus pain (n/a - Recovering/Resolving - Other Medically Important			
										Condition), Urticaria (n/a - Recovering/Resolving - Other Medically			
										Important Condition)			1 1
EU-EC- 10011067694	24/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
	24/12/2021	Spontaneous	Healthcare	European Economic	Not available			Female	No	Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
		Spontaneous Spontaneous	Healthcare Professional	European Economic Area	Not available Not available			Female	No	Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition) Nausea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not	(S - COVID-19 immunisation - Not applicable - [1d - n/a -		ICSR
EU-EC- 10011068292	24/12/2021		Non	European Economic Area European Economic Area European		12-17 Years	Specified Not Specified			Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition) Nausea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -) Chills (1d - Chills	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] COMIRNATY [TOZINAMERAN] COMIRNATY [TOZINAMERAN]	Not reported	
EU-EC- 10011068292	24/12/2021	Spontaneous	Non	European Economic Area European Economic Area European Economic	Not available	Years 12-17 Years	Specified Not Specified	Female	No	Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition) Nausea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011068292	24/12/2021	Spontaneous	Non Healthcare Professional Non Healthcare Professional	European Economic Area European Economic Area European Economic	Not available	12-17 Years	Specified Not Specified	Female	No	Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition) Nausea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -), Chills (1d - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011068292	24/12/2021	Spontaneous	Non Healthcare Professional Non Healthcare Professional	European Economic Area European Economic Area European Economic	Not available	12-17 Years	Specified Not Specified	Female	No	Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition) Nausea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -), Chills (1d - Recovered/Resolved -), Chills (1d - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Injection site pain (15d - Recovered/Resolved -), Malaise (1d -	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011068292	24/12/2021	Spontaneous	Non Healthcare Professional Non Healthcare Professional	European Economic Area European Economic Area European Economic	Not available	12-17 Years	Specified Not Specified	Female	No	Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition) Nausea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -), Chills (1d - Recovered/Not Resolved -) Chills (1d - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Injection site pain (15d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved - Recovered/Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011068292	24/12/2021	Spontaneous	Non Healthcare Professional Non Healthcare Professional	European Economic Area European Economic Area European Economic	Not available	12-17 Years	Specified Not Specified	Female	No	Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition) Nausea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -), Chills (1d - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Injection site pain (15d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved - Recovered/Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011068292 EU-EC- 10011068314	24/12/2021 24/12/2021	Spontaneous	Non Healthcare Professional Non Healthcare Professional Non Healthcare Professional	European Economic Area European Economic Area European Economic Area European Economic Area	Not available	12-17 Years	Specified Not Specified	Female	No	Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition) Nausea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -), Chills (1d - Recovered/Not Resolved -) Fatigue (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Mylagia (1d - Recovered/Resolved -), Mylagia (1d - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Not Recovered/Resolved -) Lymphadenopathy (n/a - Not Recovered/Not Recovered/Not	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported Not reported	ICSR
EU-EC- 10011068292 EU-EC- 10011068314	24/12/2021 24/12/2021 24/12/2021	Spontaneous	Non Healthcare Professional Non Healthcare Professional Non Healthcare Professional	European Economic Area European Economic Area European Economic Area European Economic Area European Economic Area	Not available Not available	12-17 Years	Specified Not Specified Not Specified	Female	No	Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition) Nausea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -) Chills (1d - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Injection site pain (15d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Not	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported Not reported	ICSR

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										Heart rate increased (2mo - Recovered/Resolved -)			
EU-EC- 10011068405	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011068412	24/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN]	[ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE ANHYDROUS] (C - Prophylaxis - n/a - [n/a - 1{DF} - n/a]), [KRILL OIL] (C - n/a - n/a - [n/a - n/a - n/a - n/a - n/a - [n/a - [n/a - n/a - [n/a - [n/a - n/a - [n/a - [n/	ICS
EU-EC- 10011068429	24/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	n/a]) Not reported	ICS
EU-EC- 10011068445	24/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Female	No	Vaginal haemorrhage (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011068495	24/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10011069826	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Depression (n/a - Unknown -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Menstrual cycle management - n/a - [n/a - n/a - Oral])	ICS
EU-EC- 10011070621	24/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10011072158	24/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (3mo - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSI
EU-EC- 10011072189	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rheumatic disorder (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011072348	24/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular])	Not reported	ICSF
EU-EC- 10011072476	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema multiforme (3wk - Recovered/Resolved -)		Not reported	ICSF
EU-EC- 10011072495	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011072571	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Subcutaneous])	Not reported	ICSF
EU-EC- 10011072594	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1(DF) - Intramuscular])	Not reported	ICSF
EU-EC- 10011072797	24/12/2021	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)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10011072929	24/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011072935	24/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Important Condition) COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS
EU-EC-	24/12/2021	Spontaneous		European	Not available	12-17	Adolescent	Female	No	Vaccination failure (n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
10011073639			Professional	Economic Area		Years				Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown -	(S - n/a - n/a - [n/a - n/a - Intramuscular])		

	l	I	l	I	I	I	1			Other Medically	l	I	
										Important Condition)			
EU-EC- 10011073646	24/12/2021	Spontaneous	Professional		Not available	12-17 Years	Adolescent	Male	No	Breast discomfort (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011073726	24/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other	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- 10011051486	23/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Pericarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Recovered/Resolved With Sequelae - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved			
										With Sequelae - Other Medically			
EU-EC-	23/12/2021	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Important Condition) Abdominal pain (n/a	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011051606	25, 12, 2521	oponeanosas		Economic	Tion are made	Years	Specified	. caic		Recovering/Resolving -),	(S - COVID-19 immunisation -	Tion reported	255.1
										Decreased appetite (n/a - Recovering/Resolving -),			
										Headache (n/a - Recovering/Resolving -),			
										Nausea (n/a - Recovering/Resolving -),			
										Pyrexia (n/a - Recovering/Resolving -),			
										Vaccination site pain (n/a - Recovering/Resolving -)			
EU-EC- 10011051720		Spontaneous Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female Female	No No	Asthenia (n/a - Unknown - Other Medically Important Condition) Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular]) COMIRNATY [TOZINAMERAN]		ICSR ICSR
10011051764	23/12/2021	Sportaneous	Professional		Not available		Specified	remale	INO	Recovering/Resolving - Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSK
										Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011052335	23/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011052716	23/12/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
			Professional	Area						Medically Important Condition), Dysmenorrhoea (n/a	Not applicable - [1d - n/a - n/a])		
										- Unknown - Other Medically Important Condition),			
										Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Immunisation (n/a - Unknown - Other Medically Important Condition),			
										Loss of personal independence in			

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										daily activities (n/a - Unknown - Other Medically Important Condition),			
										Off label use (n/a - Unknown - Other Medically Important Condition),			
										Pain in extremity (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011052	23/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
				Area						Hospitalisation, Other Medically Important Condition),	Intramuscular])		
										Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pain (n/a - Unknown -),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically			
EU-EC- 10011052	23/12/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Asthenia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
			Professional	Economic Area						Condition),	Not applicable - [1d - n/a - n/a])		
										Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Headache (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011053		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Dyspnoea (n/a - Recovered/Resolved -),			
										Pain (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011053		Spontaneous	Professional		Not available	12-17 Years	Not Specified	Female	No	Lymphadenitis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011053		Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Not Specified	Male	No		COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Oropharyngeal pain (n/a - Recovered/Resolved -),			
										Pericarditis (n/a - Not Recovered/Not Resolved -			
										Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Rhinitis (n/a - Recovered/Resolved			
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EU-EC- 10011054325	23/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Unknown -), Menstrual disorder	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICSE
										(n/a - Unknown -)		[VITAMINS NOS] (C - n/a - n/a -)	
EU-EC- 10011054337	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICSF
										Headache (n/a - Unknown -),			
										Illness (n/a - Unknown -),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved -),			
										Nasopharyngitis (n/a			
										Recovering/Resolving -)			
EU-EC- 10011054338	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
EU-EC- 10011054349	23/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Mobility decreased (5d - Recovered/Resolved -),			
										Pain in extremity (5d			
										Recovered/Resolved			
EU-EC- 10011054353	23/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICSF
EU-EC- 10011054489	23/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	·	ICSF
										Electrocardiogram change (82h - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011054537	23/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSF
										Back pain (n/a - Not Recovered/Not Resolved -), Chest discomfort			
										(n/a - Recovered/Resolved -),			
										Dyspnoea (n/a - Recovered/Resolved -),			
										Nausea (n/a - Recovered/Resolved -),			
										Neck pain (n/a - Recovered/Resolved -), Pain in extremity			
										(n/a - Recovered/Resolved			
EU-EC- 10011054576	23/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deafness (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Deafness bilateral (n/a - Unknown - Other Medically Important Condition),			
										Tinnitus (n/a - Unknown -)			
EU-EC- 10011054578	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (n/a - Unknown -), Oculomucocutaneous syndrome (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF

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										Pruritus (n/a - Unknown -),			
										Pyrexia (n/a - Not Recovered/Not			
										Resolved -), Rash (n/a - Not Recovered/Not Resolved -),			
										Urticaria (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011054645	23/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	(n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Glomerulonephritis chronic (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Haematuria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										IgA nephropathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Proteinuria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Vasculitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011054674		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		ICSR
EU-EC- 10011054715	23/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Resolved - Other Medically Important Condition)			
EU-EC- 10011055312	23/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC- 10011055315	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011055381	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Headache (n/a - Recovered/Resolved -), Lymphadenopathy			
										(n/a - Not Recovered/Not Resolved -), Myalgia (n/a -			
										Recovered/Resolved -), Pyrexia (n/a -			
EU-EC- 10011056537	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -) Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICSR
EU-EC- 10011056540	23/12/2021	Spontaneous	Non	European Economic	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (3d - Not Recovered/Not Resolved -),	- n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Heavy menstrual bleeding (6d - Recovered/Resolved -),	.4441)		
										Hypomenorrhoea (3d			

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										Injection site pain (3d - Recovered/Resolved			
										Menstruation delayed			
										Recovered/Resolved			
										Polymenorrhoea (3d			
										Recovered/Resolved -)			
EU-EC- 10011056543		Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (91d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		ICSR
EU-EC- 10011057561	23/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Depressed level of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Lethargy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Presyncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pulmonary embolism (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Throat tightness (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation), Vision blurred (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011057570	23/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Encephalitis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Eye movement disorder (n/a - Unknown -),			
										Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011057588	23/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Chest discomfort (n/a - Not Recovered/Not			

											Resolved -			
											Caused/Prolonged Hospitalisation),			
											Dizziness (n/a - Not Recovered/Not Resolved -			
											Caused/Prolonged Hospitalisation),			
											Dyspnoea (n/a - Not Recovered/Not			
											Resolved - Caused/Prolonged			
											Hospitalisation),			
											Feeling of body temperature change (n/a - Not			
											Recovered/Not Resolved - Caused/Prolonged			
											Hospitalisation),			
											Headache (n/a - Not Recovered/Not Resolved -			
											Caused/Prolonged Hospitalisation),			
											Nausea (n/a - Not Recovered/Not			
											Resolved - Caused/Prolonged			
											Hospitalisation), Paraesthesia (n/a -			
											Not Recovered/Not Resolved -			
											Caused/Prolonged Hospitalisation),			
											Periorbital oedema (n/a - Not			
											Recovered/Not Resolved - Caused/Prolonged			
											Hospitalisation),			
											Syncope (n/a - Not Recovered/Not Resolved -			
											Caused/Prolonged Hospitalisation, Other Medically			
											Important Condition),			
											Urticaria (n/a - Not Recovered/Not			
											Resolved - Caused/Prolonged			
											Hospitalisation), Vaccination site pain			
											(n/a - Not Recovered/Not			
											Resolved - Caused/Prolonged Hospitalisation),			
											Vision blurred (n/a - Not Recovered/Not			
											Resolved - Caused/Prolonged			
E	U-EC-	23/12/2021	Spontaneous		Non	Not available		Not	Female	No		COMIRNATY [TOZINAMERAN]	Not reported	ICSR
1	0011057680			Professional	European Economic Area		Years	Specified			(n/a - Recovering/Resolving - Other Medically	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
											Important Condition),			
											Angioedema (n/a - Recovering/Resolving			
											- Other Medically Important Condition),			
											Feeling of body			
											temperature change (n/a - Recovering/Resolving			
											Recovering/Resolving - Other Medically Important			
											Condition), Flushing (n/a -			
											Recovering/Resolving - Other Medically Important			
											Condition),			
											Nausea (n/a - Recovering/Resolving - Other Medically			
											Important Condition),			
											Swelling (n/a - Recovering/Resolving			
											- Other Medically Important Condition),			
											Throat tightness (n/a			
											- Recovering/Resolving			

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										- Other Medically Important Condition),			
										Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Vision blurred (n/a - Recovering/Resolving - Other Medically			
EU-EC-	23/12/2021	Spontaneous		Non	Not available			Male	No	Important Condition) Arthralgia (102h -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011057704				European Economic Area		Years	Specified			Recovered/Resolved -), Chest pain (102h - Recovered/Resolved	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										-), Myocardial necrosis marker increased (5d			
										- Recovered/Resolved - Other Medically Important Condition),			
										Myocarditis (102h - Recovered/Resolved - Other Medically Important			
										Condition), Pyrexia (102h - Recovered/Resolved			
EU-EC- 10011057758	23/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Aneurysm (n/a - Fatal - Results in Death),	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not	Not reported	ICSR
			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Area						Cerebellar haemorrhage (n/a - Fatal - Results in Death),	applicable - [1d - n/a - n/a])		
										Dizziness (n/a - Fatal - Results in Death),			
										Headache (n/a - Fatal - Results in Death),			
										Loss of consciousness (n/a - Fatal - Results in Death),			
										Subarachnoid haemorrhage (n/a - Fatal - Results in Death),			
										Subdural haematoma (n/a - Fatal - Results in Death),			
EU-EC-	23/12/2021	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No	Vomiting (n/a - Fatal - Results in Death) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011057881			Professional			Years				Unknown - Other Medically Important Condition), Vaccination failure	(S - n/a - n/a - [n/a - n/a - Intramuscular])	,	
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011057897	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other	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- 10011058125	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (61d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011058306	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dressler's syndrome (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Exercise tolerance decreased (n/a - Unknown -),			
										Fatigue (n/a - Unknown -),			
EU-EC-	73/13/2024	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Malo	No	Myocarditis (n/a - Unknown - Other Medically Important Condition) Fatigue (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011058311	23/12/2021	Spontaneous	Professional		INOL AVAIIADIE	Years	Audiescent	riale	INU	Recovered/Not Resolved -),	(S - n/a - n/a - [n/a - n/a - Intramuscular])	mot reported	ICSK
										Headache (n/a - Not			

					I	I			1	Recovered/Not			
EU-EC- 10011058354	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Crying (n/a - Recovering/Resolving -), Headache (n/a -			
										Recovering/Resolving -), Nausea (n/a -			
										Recovering/Resolving -), Pain (n/a - Recovering/Resolving			
EU-EC- 10011058621	23/12/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Paraesthesia (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR
EU-EC- 10011058639	23/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Male	No	-) Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oral herpes (n/a -	- n/a - n/a]) COMIRNATY [TOZINAMERAN] COS - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
										Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011058652	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (1d - Recovered/Resolved -), Headache (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Recovered/Resolved -), Myalgia (1d - Recovered/Resolved			
										-), Nausea (1d - Recovered/Resolved			
										Pyrexia (1d - Recovered/Resolved			
EU-EC- 10011058805	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011059445	23/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -), Lipase increased (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Pancreatitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011059851	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
				_						Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011059882	23/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011059905	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Oesophageal achalasia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011059970	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (78d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Herpes zoster meningitis (78d - Recovered/Resolved - Other Medically Important Condition),			
										Intracranial pressure increased (78d - Recovered/Resolved - Other Medically Important Condition)			

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EU-EC- 10011060225	23/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes simplex (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICS
EU-EC- 10011060248	23/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ear infection (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011060252	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (12h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011060375	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - n/a])	Not reported	ICSF
EU-EC- 10011060402	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011060418	23/12/2021	Spontaneous		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	ICSF
EU-EC- 10011060641	23/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disorientation (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (0d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										- Other Medically Important Condition), Emotional distress (n/a - Unknown -			
										Other Medically Important Condition), Headache (n/a -			
										Recovering/Resolving - Other Medically Important Condition),			
										Paraesthesia (1d - Recovered/Resolved - Other Medically Important Condition),			
										Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011060648	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Swelling (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10011060675	23/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Gait inability (n/a - Unknown - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
										Malaise (n/a - Unknown - Disabling), Nerve injury (n/a -			
										Not Recovered/Not Resolved - Disabling), Suspected COVID-19			
										(n/a - Unknown - Disabling), Syncope (n/a -			
										Recovered/Resolved With Sequelae - Disabling)			
EU-EC- 10011060690	23/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (20min - Recovered/Resolved -), Syncope (20min - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011060708	23/12/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Male	No	Important Condition Abdominal pain (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSF
13011000/08				Economic Area		icals	эрсинеи			- Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Appendicitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Condition),			

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										Nausea (n/a - Unknown -),			
										Vomiting (n/a -			
EU-EC- 10011060977	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Unknown -) Asthenia (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]	Not reported	ICS
										Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition),	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Hyperhidrosis (n/a - Recovered/Resolved - Other Medically Important Condition),			
EU-EC-	22/12/2021	Spontaneous	Hoaltheare	European	Not available	12-17	Adolescent	Fomalo	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICC
10011061049	23/12/2021	Spontaneous	Professional	European Economic Area	NOT available	Years	Adolescent	remale	INO	Eye pain (n/a - Recovered/Resolved - Other Medically	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}	Not reported	ICS
EU-EC- 10011061617	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Bell's palsy (n/a - Recovering/Resolving - Other Medically Important Condition)	Not applicable - [n/a - n/a -	Not reported	ICS
EU-EC- 10011061646	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	NOVORAPID [INSULIN ASPART] (C - Type 1 diabetes mellitus - n/a - [n/a - n/a - n/a])	ICS
										Immunisation (n/a - Unknown - Other Medically Important Condition),			
FIL FC	22/12/2021	Casabaassa	Haalibaassa	Non	Nat available	12.17	Net	Mala	Ne	Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)		Nebroseded	TCC
EU-EC- 10011061657	23/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICS</u>
										Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Loss of consciousness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Rash (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011061999	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICS

										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011062041	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination failure (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011062367	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye movement disorder (5min - Unknown - Life Threatening), Seizure like phenomena (5min - Unknown - Life Threatening, Other	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	23/12/2021	Spontaneous	Healthcare	European	Not available	12-17	Not	Female	No	Medically Important Condition), Tremor (5min - Unknown - Life Threatening) Long QT syndrome	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011062466	25,12,2521	эропкапова	Professional			Years	Specified	. cinale		congenital (n/a - Fatal - Results in Death, Other Medically Important Condition), Sudden cardiac	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	oc iopolica	<u> </u>
										death (n/a - Fatal - Results in Death, Other Medically Important Condition)			
EU-EC- 10011062604	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU EC	22/42/2024				Not and the last	12.17		I-	N.	Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMPAND (TOTAL MEDIA)	N.A.	Toco
EU-EC- 10011062758	23/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
						12.12				(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011063128		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Fatigue (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011063155	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC- 10011063292	23/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Adolescent	Male	No	-) Arthralgia (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Fatigue (n/a - Recovered/Resolved -),			
										Headache (n/a - Recovered/Resolved -),			
										Myalgia (n/a - Recovered/Resolved -), Pyrexia (n/a -			
EU EO	22/42/2024		N	-	No. 2 - No. 1	42.47	N			Recovered/Resolved -) Asthenia (n/a -	COMPULATO TOTAL AMERICAN	No.	TOOD
EU-EC- 10011063327	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Disorientation (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Visual impairment (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011063364	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -), Diarrhoea (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

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E-FC DISTRICT STATE AND ADDRESS OF THE PROPERTY OF THE PROPERT														
DACK DATE Decision Decision											Headache (n/a -			
Section Commission Commis											Vaccination site pain			
2012-02-20 Spentaneous Federator Format November 12-70 November 12-10 Nov														
Secretary (1997) ELEC. 2012/2021 Southware New York (1997) ELEC. 2		23/12/2021	Spontaneous	Healthcare		Not available			Female	No	Unknown -) Dizziness (10min -	COMIRNATY [TOZINAMERAN]	Not reported	ICSF
ELECT 2322/2012 Sovetenesces Information of the production of the	10011063530			Professional	Economic		Years	Specified				Not applicable - [1d - n/a -		
Perfection of Professional Programs Professional Profes											Recovered/Resolved - Other Medically	-		
PLACE TO THE STATE OF THE STATE		23/12/2021	Spontaneous		European Economic	Not available			Female	No	Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSF
Canada Principal Canada Prin											Condition), Dyspnoea (n/a - Not Recovered/Not			
EL-45- Distribution Applications Applicati											Caused/Prolonged Hospitalisation, Other Medically Important			
Recoveragified in Registration (Program of Reg											Unknown - Caused/Prolonged Hospitalisation, Other Medically Important			
EU-EC- 100.1106/38974 23/12/2021 Spontaneous Non Hod wallable 12-17 Not will be reported 100.1106/38974 100.1106/38974 23/12/2021 Spontaneous Non Hod wallable 102-17 Not will be reported 100.1106/38974 100.1106/38974											Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important			
ELEC- 23/12/2021 Spontaneous Non Healthcare European Professional Economic Area											(n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important			
Healthcare Professional Profess		22/12/2021		Nec	Nov	N. A. C.	12.17	Net	Mala	N-	Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMPANY (TO JAMES AN)		Teer
Recovering/Resolving - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - New Friend		23/12/2021	Spontaneous	Healthcare	European Economic	Not available			маю	NO	Recovering/Resolving - Other Medically Important	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSF
Unknown - Other Medically Important Condition), Decreased appetite (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Heat exhaustion (n/a - Unknown - Other Medically Important Condition), Heat exhaustion (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - Other											Recovering/Resolving - Other Medically Important			
(n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Heat exhaustion (n/a - Unknown - Other Medically Important Condition), Heat exhaustion (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - Other Medically Important Condition),											Unknown - Other Medically Important			
Unknown - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Heat exhaustion (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - Other											(n/a - Recovering/Resolving - Other Medically Important			
Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Heat exhaustion (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - Other											Unknown - Other Medically Important			
Recovering/Resolving - Other Medically Important Condition), Heat exhaustion (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - Other											Unknown - Other Medically Important			
- Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - Other											Recovering/Resolving - Other Medically Important			
Unknown - Other											- Unknown - Other Medically Important			
											Insomnia (n/a - Unknown - Other Medically Important			

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										Condition), Lethargy (10d - Recovered/Resolved - Other Medically Important Condition),			
										Nasal mucosal disorder (n/a - Unknown - Other Medically Important Condition),			
										Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (8d - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 100110638		Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haemorrhage intracranial (n/a - Recovering/Resolving - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 100110639		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Unknown -), Malaise (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
										Pyrexia (n/a - Unknown -)			
EU-EC- 100110641	02	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent		No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC- 100110641		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Unknown -), Malaise (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
										Pyrexia (n/a - Unknown -)			
EU-EC- 100110641		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 100110642		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	HYDROCHLORIDE] (C - Sinus congestion - n/a - [n/a - n/a -	ICSR
										Headache (n/a - Recovering/Resolving - Caused/Prolonged		n/a])	
										Hospitalisation), Influenza like illness (n/a - Unknown - Caused/Prolonged			
										Hospitalisation), Malaise (n/a - Recovering/Resolving - Caused/Prolonged			
										Hospitalisation), Meningoencephalitis viral (n/a - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovering/Resolving			
										- Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a -			
										Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
EU-EC-	23/12/2024	Spontaneous	Non	Non	Not available	12-17	Not	Female	No	Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) Chest pain (0d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
100110644	64	Sportaneous		European	INUL AVAIIDUR	Years	Specified	remale	INU	Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	постеропеа	ICSK
										Dyspnoea (1d - Recovered/Resolved - Other Medically Important Condition),			

							,		LIOUN	y report	ı		
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Movement disorder (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Palpitations (0d - Recovered/Resolved - Other Medically Important Condition),			
										Visual impairment (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011064554	23/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye swelling (1d -	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011036780	22/12/2021	Spontaneous	Non	European Economic	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Nausea (n/a - Recovered/Resolved -)			
EU-EC- 10011037200	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Recovered/Not Resolved -),			
										Decreased appetite (n/a - Not Recovered/Not Resolved -),			
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Pallor (n/a - Not Recovered/Not Resolved -),			
										Vaccination site pain (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011037374		Spontaneous	Professional	Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (20d - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		ICSR
EU-EC- 10011037376	22/12/2021	Spontaneous	Healthcare Professional		Not available		Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011037386	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011037401	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Gait disturbance (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} -	Not reported	ICSR
										Lymphadenopathy (n/a - Unknown -), Migraine (n/a -	Intramuscular])		
EU-EC-	22/12/2021	Spontaneous		European	Not available	12-17	Not	Male	No	Unknown -) Hyperpyrexia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011037415				Economic Area		Years	Specified			Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EUEC	22/12/2021	Cnonton	Non	Europa	Not available	12.17	Not	Mala	No	Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIDNATY ITOZINAMEDANI	Not reported	ICCD
EU-EC- 10011037419	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	пиос герогсеа	<u>ICSR</u>
										Somnolence (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-	22/12/2021	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Asthenia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>

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10011037490			Healthcare Professional			Years	Specified			Recovering/Resolving - Disabling), Headache (n/a - Recovering/Resolving - Disabling), Presyncope (n/a - Recovering/Resolving - Disabling), Vertigo (n/a - Recovering/Resolving - Disabling), Vomiting (n/a -	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
										Recovering/Resolving - Disabling)			
EU-EC- 10011037876		Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	 	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		ICSR
EU-EC- 10011037890	22/12/2021	Spontaneous		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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011037895	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Syncope (15min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011037900	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011037922	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Unknown - Other Medically Important Condition), Systemic viral	.,	Not reported	ICSR
										infection (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011037925	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Febrile convulsion (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
EU-EC- 10011037929	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011037941	22/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Unknown -), Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011037951	22/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Bradycardia (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011037952	22/12/2021	Spontaneous		Area Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) C-reactive protein increased (n/a - Recovering/Resolving -), Chest X-ray abnormal (n/a -	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Recovering/Resolving -), Chest pain (n/a -			
										Recovering/Resolving -), Echocardiogram abnormal (n/a -			
										Recovering/Resolving -), Electrocardiogram			
										abnormal (n/a - Recovering/Resolving -), Myocarditis (n/a -			
										Recovering/Resolving - Other Medically Important Condition),			
										Troponin I abnormal (n/a - Recovering/Resolving -),			
										Troponin T increased (n/a - Recovering/Resolving -)			

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EU-EC- 10011037963	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pruritus (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Rash (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011037996	22/12/2021	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 - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011038001	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011038024	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (3578min - Recovered/Resolved -), Headache (3578min	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved			
										Injection site hypoaesthesia (n/a - Unknown -),			
										Nausea (3578min - Recovered/Resolved -),			
										Pyrexia (3578min - Recovered/Resolved -),			
EU-EC-	22/12/2021	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Syncope (3578min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011038028	22/12/2021	Spontaneous	Healthcare	European Economic Area	NUL available	Years	Specified	Male	NO	Recovered/Not Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Inappropriate schedule of product administration (n/a - Unknown -),			
										Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011038034	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Limb discomfort (2d			
										Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition)			
10011038044		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		ICSR
EU-EC- 10011038049	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Malaise (0d - Recovered/Resolved - Other Medically Important Condition),			
										Nasopharyngitis (0d - Recovered/Resolved			
									1	- Other Medically			

EU-EC- 10011038050 22/										Pallor (0d -			
										Recovered/Resolved - Other Medically Important Condition),			
										Syncope (0d - Recovered/Resolved - Other Medically			
	2/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Syncope (10min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011038052	2/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),		Not reported	ICSR
										Vaccination site pain (n/a - Recovered/Resolved -)			
EU-EC- 10011038054	2/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Immunisation (n/a - Unknown - Other Medically Important Condition),			
										Off label use (n/a - Unknown - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC- 10011038206	2/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition) Dizziness (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011038207	2/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										-), Syncope (n/a - Recovered/Resolved - Other Medically			
EU-EC- 10011038232	2/12/2021			Economic	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Body temperature increased (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Fatigue (0d - Recovered/Resolved -),	,		
										Hypotension (n/a - Unknown -), Loss of consciousness (n/a -			
										Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011038243	2/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	not reported	<u>ICSR</u>
EU-EC- 22/	2/12/2021	Spontaneous		Non	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Confusional state (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
10011036236			Professional	European Economic Area		Years	Specified			Headache (n/a - Unknown -),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
										Malaise (n/a - Unknown -),			

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										Unknown - Other Medically Important Condition)			
J-EC- 0011038260	22/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Dizziness (n/a - Unknown - Other Medically Important Condition),			
										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Feeling hot (n/a - Unknown - Other Medically Important Condition),			
										Illness (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (0d - Recovered/Resolved - Other Medically Important Condition),			
										Syncope (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
·EC-	22/12/2021	Spontaneous	Hoaltheare	Non	Not available	12-17	Adolescent	Malo	No	Vomiting (0d - Recovered/Resolved - Other Medically Important Condition) Chest pain (n/a -	[BISOPROLOL, BISOPROLOL	[COLCHICINE] (C -	IC
11038546	22/12/2021	Spontaneous		European Economic Area	Not available	Years	Adolescent	Male	No	Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),		n/a - Drug withdrawn	
										Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	for unknown indication - Unknown - [n/a - n/a - n/a]), [TOZINAMERAN] (S - Immunisation - Not applicable - [1d - n/a - n/a])		
										Discharge (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Genitourinary symptom (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Sinus bradycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Vomiting (n/a - Recovered/Resolved - Caused/Prolonged			

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										Other Medically Important Condition)			
U-EC- 0011038563	22/12/2021	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 - n/a])		ICS
:U-EC- 0011038569	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
U-EC- 0011038583	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
U-EC- 0011038591	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -), Syncope (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Recovered/Resolved - Other Medically Important Condition)			
U-EC- 0011038612	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Abdominal rigidity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
:U-EC- .0011038628	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic shock (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										Hypotension (n/a - Unknown -),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Shock (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
:U-EC- .0011038632	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Syncope (n/a - Unknown - Other Medically Important Condition)			
:U-EC- .0011038633	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										-), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
:U-EC- .0011038636	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Atonic seizures (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Electrocardiogram ambulatory abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Orthostatic intolerance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Somatic symptom disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
						1	1	I		Hospitalisation),			

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										Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
EU-EC- 10011038642		Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hospitalisation) Malaise (75min - Recovered/Resolved -), Syncope (5min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										- Other Medically Important Condition)			
EU-EC- 10011038656		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (1h - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Pallor (1h - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011039256	22/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Facial paresis (n/a - Recovering/Resolving -), Hypoaesthesia (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	<u>ICSR</u>
										Recovering/Resolving -), Nausea (n/a - Recovering/Resolving			
EU-EC- 10011039388		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 - [n/a - n/a - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),			
										Fatigue (n/a - Unknown - Other Medically Important Condition),			
										Immune system disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Influenza (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Malaise (n/a - Unknown - Other Medically Important Condition),			
										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Nasopharyngitis (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),			
EU-EC-	22/12/2021	Spontaneous	Healthcare	Non	Not available	12-17	Not	Female	No	Tachycardia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011039432		Sportaneous	Professional			Years	Specified	Citale		(0d - Recovered/Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		<u>100R</u>
										Anxiety (n/a - Unknown -), Chest pain (n/a -			
										Unknown -), Dyspnoea (n/a -			
										Recovering/Resolving			

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										- Other Medically Important Condition),			
										Malaise (n/a - Unknown -),			
										Pallor (n/a - Recovering/Resolving -),			
										Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition),			
										Speech disorder (n/a - Unknown - Other Medically Important Condition),			
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011039460	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (6930min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Loss of consciousness (6930min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011039478	22/12/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
				Economic Area						Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	Not applicable - [1d - n/a - Intramuscular])		
										Dysuria (n/a - Unknown -),			
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011039485	22/12/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR
				Economic Area						Hypoaesthesia (n/a - Unknown -),	Not applicable - [1d - n/a - Intramuscular])		
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011039496	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011039505	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown -), Heart rate increased	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
				Alea						(n/a - Unknown -), Myocarditis (n/a -	Intrantoscular j)		
										Recovering/Resolving - Other Medically Important Condition),			
										Ventricular tachycardia (n/a - Unknown - Other Medically Important Condition),			
FUEC	22/42/222	Cnarte	Health -	Non	Not over!-!-!-	12.77	Not	Farre	Ne	Vomiting (n/a - Unknown -)	COMIDNATA (TOTIVAMES 4	Not your tod	Icco
EU-EC- 10011039514	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	INOT REPORTED	<u>ICSR</u>
										Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011039519	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bradycardia (20min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (20min -			

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										Recovered/Resolved			
										Hypotension (20min			
										- Recovered/Resolved			
										-),			
										Pallor (20min - Recovered/Resolved -)			
EU-EC- 10011039980	22/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Female	No	COVID-19 immunisation (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	<u>ICSR</u>
			Professional								n/a]),		
										Disabling),	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-		
										Type 1 diabetes mellitus (n/a -	024414)] (S - n/a - n/a - [1d - n/a - n/a])		
										Recovered/Resolved With Sequelae -			
	22/12/2021	Spontaneous		Non	Not available	12-17	Not	Female	No	Disabling) Hypopnoea (n/a -	COMIRNATY [TOZINAMERAN]		ICSR
10011040090			Professional	Economic		Years	Specified			Not Recovered/Not Resolved -),	(S - COVID-19 immunisation - Not applicable - [1d - n/a -	- n/a - n/a - [n/a - n/a - Ophthalmic]),	
				Area						Nephrotic syndrome	Intramuscular])	[BEPOTASTINE BESILATE] (C - n/a -	
										Recovering/Resolving - Other Medically		n/a - [n/a - n/a - Oral]),	
										Important Condition),		[MONTELUKAST,	
										Oedema peripheral		MONTELUKAST SODIUM] (C - n/a -	
										(n/a - Not Recovered/Not		n/a - [n/a - n/a - Oral])	
										Resolved -),			
										Protein urine present (n/a - Not			
										Recovered/Not Resolved - Other Medically Important			
										Condition),			
										Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Weight increased (n/a - Not			
										Recovered/Not Resolved -)			
EU-EC- 10011040219	22/12/2021	Spontaneous	Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not		(C - Immunisation -	<u>ICSR</u>
			Professional	Area Area							Not applicable - [1d - n/a - n/a])	n/a - [1d - n/a - n/a])	
										Condition), Hiccups (n/a - Not			
										Recovered/Not Resolved - Other			
										Medically Important Condition),			
										Musculoskeletal			
										chest pain (n/a - Not Recovered/Not Resolved - Other			
										Medically Important Condition)			
EU-EC- 10011040228	22/12/2021	Spontaneous		Non European	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
100110 10220			Trorcasional	Economic Area		icuis	Specifica				Not applicable - [1d - n/a - Intramuscular])		
										Important Condition),	,		
										Rash (n/a - Unknown			
										- Other Medically Important			
										Condition), Urticaria (n/a -			
										Unknown - Other Medically Important			
EU-EC-	22/12/2021	Spontaneous	Healthcare	Non	Not available	12-17	Not	Female	No	Condition) Chest pain (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011040237				European Economic		Years	Specified				(S - COVID-19 immunisation - Not applicable - [1d - n/a -		_
				Area						Dyspnoea (n/a -	n/a])		
										Recovering/Resolving -),			
										Electrocardiogram ST segment elevation			
										(n/a - Recovering/Resolving			
										- Other Medically Important			
										Condition), Pericarditis (n/a -			
										Recovering/Resolving - Other Medically			
										Important Condition),			
										Tachycardia (n/a -			
FILE -	DO 1/1 - 11					15.				Recovering/Resolving			
EU-EC- 10011040241	22/12/2021	Spontaneous		Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	<u>ICSR</u>
				Area						Recovered/Resolved - Other Medically Important Condition)	Not applicable - [1d - n/a - Intramuscular])		
⊣ nttns://dan.e	ma aurai	oo oulono	ı İvtice/caw	disco	1	1	1	1	1	amportant condition)	1	1	44/62

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EU-EC- 10011040248	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),	,		
										Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pain (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),			
										Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011040266	22/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (2h - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011040281	22/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011040293	22/12/2021	Spontaneous	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 - [1d - n/a - Intramuscular])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011040297	22/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Nausea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -), Syncope (n/a - Recovered/Resolved			
										- Other Medically Important Condition),			
EU-EC-	22/12/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Vision blurred (n/a - Recovered/Resolved -) COVID-19	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011040445	,,			Economic		Years				immunisation (n/a -	(S - n/a - n/a - [n/a - n/a - n/a])		
										Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Heart rate variability increased (n/a - Not Recovered/Not Resolved - Other Medically Important			
										Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC- 10011040456	22/12/2021	Spontaneous		Economic	Not available	12-17 Years	Adolescent	Female	No	-	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
			Troressional	Aicu						- Other Medically Important Condition),	1,141)		
										Decreased appetite (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Dysphagia (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Flank pain (n/a - Recovered/Resolved - Other Medically Important			
										Condition), Nasopharyngitis (n/a			
I		l	I	l	l		I	I		l			

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										Recovered/Resolved - Other Medically Important Condition),			
										Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),			
										SARS-CoV-2 test negative (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Sensation of foreign body (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011040788	22/12/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No	Essential tremor (n/a - Not Recovered/Not Resolved -), Injection site pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										(2d - Recovered/Resolved -)			
EU-EC- 10011040793	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arrhythmia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Chills (n/a - Recovering/Resolving -), Fatigue (n/a -			
										Recovering/Resolving			
										Hyperpyrexia (n/a - Recovering/Resolving -), Malaise (n/a -			
EU-EC-	22/12/2021	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No	Recovering/Resolving -) Chills (3d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011040890	22/12/2021	Sportaneous	Professional		Not available	Years	Adolescent	remaie		Recovered/Resolved - Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSIX
										Headache (2d - Recovered/Resolved -),			
										Influenza like illness (3d - Recovered/Resolved -),			
										Syncope (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011041316	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011041623	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (50d - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Lymphoma (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011042043	22/12/2021	Spontaneous	Professional		Not available	12-17 Years	Adolescent	Female	No	Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a3mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011042542	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (3d - Recovered/Resolved -), Malaise (3d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
										Recovered/Resolved -), Myalgia (3d - Recovered/Resolved			
EU-EC- 10011042592	22/12/2021	Spontaneous	Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	-) Tinnitus (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a -	Not reported	ICSR
EU-EC- 10011042607	22/12/2021	Spontaneous	Professional Healthcare Professional	European	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -),	n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a3mL - n/a])	Not reported	ICSR
										Menstrual disorder (n/a - Not Recovered/Not Resolved -)			

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EU-EC- 10011042993	22/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Hypotension (n/a - Unknown - Disabling), Loss of personal independence in daily activities (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011043040	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Disabling) Dizziness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICS
										Headache (n/a - Not Recovered/Not Resolved -), Muscle twitching (n/a - Not			
										Recovered/Not Resolved -), Nervous system			
										disorder (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011043063	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICS
										Lymphadenopathy (n/a - Recovered/Resolved -)			
EU-EC- 10011043284	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICS
										Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation),	MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC- 10011043367	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (6d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - .3mL - n/a])	Not reported	ICS
										Headache (6d - Recovered/Resolved -),			
										Injection site pain (6d - Recovered/Resolved -),			
										Pyrexia (6d - Recovered/Resolved -)			
EU-EC- 10011043458	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase increased (5d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[CARBOCISTEINE] (C - Upper respiratory tract inflammation - n/a - [6d - n/a - Oral]),	ICSF
										Disease recurrence (n/a - Not Recovered/Not Resolved -),		[CEFDITOREN PIVOXIL] (C - Upper respiratory tract inflammation - n/a -	
										Headache (n/a - Not Recovered/Not Resolved -),		[6d - n/a - Oral]), [PARACETAMOL] (C - Upper respiratory	
										Malaise (n/a - Not Recovered/Not Resolved -),		tract inflammation - n/a - [6d - n/a - Oral])	
										Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pharyngeal erythema (n/a - Not Recovered/Not Resolved -),			
										Productive cough (n/a - Not Recovered/Not			
										Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -),			
										Rhinorrhoea (n/a - Not Recovered/Not Resolved -),			
										Upper respiratory tract infection (n/a - Unknown -)			
EU-EC- 10011043603	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal discomfort (0d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a3mL - Intramuscular])	Not reported	ICSR
:ps://dap.e	ma auran		hytios/sow	disco						Abdominal pain (1d -			47/

	22/12/2021	Spontaneous			Not available		Adolescent	Female	No	Recovered/Resolved - Caused/Prolonged Hospitalisation), Body temperature increased (0d - Recovered/Resolved -), Diarrhoea (0d - Recovered/Resolved -), Fatigue (7d - Recovered/Resolved -), Headache (5d - Recovered/Resolved -), Lip oedema (6d - Recovered/Resolved -), Multisystem inflammatory syndrome in children (4d - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -), Rash (6d - Recovered/Resolved -), Syncope (0d - Recovered/Resolved -) Application site pain	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011043663			Professional			Years				(n/a - Recovered/Resolved -), Chills (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -),	(S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])		
EU-EC- 10011043816	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified		No	Encephalitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011043845	22/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
10011043850		Spontaneous	Healthcare Professional	Area	Not available Not available	12-17 Years	Not Specified		No	Fatigue (n/a - Unknown - Other Medically Important Condition), Haemoptysis (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition) Angioedema (n/a -	[TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
10011043870	-211212021	ыропtaneous		European Economic Area	not available	12-17 Years	Not Specified	, entale	INU	Angioedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Face oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Flushing (n/a -	COMENTAL FOR CONTENT RATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a3mL - Intramuscular])	Not reported	<u>ICSK</u>

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											Unknown - Caused/Prolonged Hospitalisation),			
											Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),			
											Rash (n/a - Unknown - Caused/Prolonged			
											Hospitalisation), Visual impairment (n/a - Unknown - Caused/Prolonged			
EU-		22/12/2021	Spontaneous			Not available	12-17	Adolescent	Male	No	Hospitalisation) COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
100	11044055			Professional	Economic Area		Years				Unknown - Other Medically Important Condition),	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
											Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
100	EC- 11044105		Spontaneous	Professional		Not available	12-17 Years	Not Specified	Female	No	Vaccination failure (12d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	·	<u>ICSR</u>
EU- 100	EC- 11044306	22/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	<u>ICSR</u>
											Chest pain (n/a - Not Recovered/Not Resolved -),			
											Chills (n/a - Not Recovered/Not Resolved -),			
											Dyspnoea (n/a - Not Recovered/Not Resolved -),			
											Echocardiogram (n/a - Not Recovered/Not Resolved -),			
											Headache (n/a - Not Recovered/Not Resolved -),			
											Lethargy (n/a - Not Recovered/Not Resolved -),			
											Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Nausea (n/a - Not Recovered/Not Resolved -),			
											Pain in jaw (n/a - Not Recovered/Not Resolved -),			
											Troponin increased (n/a - Not Recovered/Not Resolved -)			
EU- 100	EC- 11044314	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	ICSR
					Area						Dyspnoea (n/a - Unknown -),	n/a])		
											Myocarditis (n/a - Unknown - Other Medically Important Condition)			
EU- 100	EC- 11044317	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
											Fatigue (n/a - Recovering/Resolving -),			
											Generalised tonic- clonic seizure (n/a - Recovering/Resolving - Other Medically			
											Important Condition), Urinary incontinence (n/a -			
											Recovering/Resolving -), Vomiting (n/a -			
EU-	FC-	22/12/2024	Spontaneous	Healthcaro	Non	Not available	12-17	Not	Male	No	Recovering/Resolving -)	COMIRNATY ITOTINAMEDANI	Not reported	ICSR
	11044329	22/12/2021	Spontaneous		European Economic Area	INOT AVAILABLE	Years	Specified	riale	No	Chest pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	woc reported	ICOK
											Electrocardiogram ST segment elevation			

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										(n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition),			
										Pyrexia (n/a - Recovered/Resolved			
EU-EC- 10011044337	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Dyspnoea (n/a - Recovering/Resolving -),			
										Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC- 10011044387	22/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Drug ineffective (n/a - Unknown - Other Medically Important Condition),			
										Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011044392	22/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
										Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011044465	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination failure (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011044631		Spontaneous	Professional	Area	Not available	12-17 Years	Not Specified	Not Specified	No		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		ICSR
EU-EC- 10011044692	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)		[DESOGESTREL] (C - Contraception, Dysmenorrhoea - n/a - [n/a - n/a - n/a])	<u>ICSR</u>
EU-EC- 10011044698	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										Fatigue (n/a - Not Recovered/Not Resolved -),			
										Headache (n/a - Not Recovered/Not Resolved -),			
										Menstruation irregular (n/a - Not Recovered/Not Resolved -)			
EU-EC- 10011045120	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Chills (n/a - Unknown -),			
										Fatigue (n/a - Unknown -),			
										Headache (n/a - Unknown -), Pyrexia (n/a -			
EU-EC-	22/12/2021	Spontaneous		European	Not available	12-17	Adolescent	Male	No	Unknown -) Ataxia (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	<u>ICSR</u>
10011045367			Professional	Economic Area		Years				Recovered/Not Resolved - Other Medically Important Condition),	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
										Diabetes mellitus inadequate control (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC- 10011045426	22/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition) Hypoacusis (n/a - Recovering/Resolving - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

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										Vestibular neuronitis (n/a - Recovering/Resolving - Caused/Prolonged	Not applicable - [1d3mL - Intramuscular])		
EU-EC- 10011045483	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hospitalisation) Ischaemic stroke (n/a - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
EU-EC- 10011045838	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hospitalisation) Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSF
										Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved -			
										Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Not			
										Recovered/Not Resolved - Caused/Prolonged Hospitalisation),			
										Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged			
										Hospitalisation), Somnolence (n/a - Not Recovered/Not Resolved -			
										Caused/Prolonged Hospitalisation)			\perp
10011045863		Spontaneous	Professional	Area	Not available	Years	Adolescent		No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular])		ICSR
EU-EC- 10011046042		Spontaneous	Healthcare Professional		Not available	12-17 Years	Adolescent		No	Epistaxis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		ICSR
10011046146		Spontaneous	Professional	Area	Not available	12-17 Years	Adolescent		No	Palpitations (n/a - Not Recovered/Not Resolved -)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSF
10011046214		Spontaneous	Professional	Area	Not available	Years	Adolescent		No	Epistaxis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	·	ICSF
EU-EC- 10011046216	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ageusia (n/a - Not Recovered/Not Resolved -), Anosmia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
										Decreased appetite (n/a - Not Recovered/Not Resolved -),			
										Influenza like illness (n/a - Not Recovered/Not Resolved -),			
										Injection site discomfort (2d - Recovered/Resolved -),			
										Insomnia (n/a - Not Recovered/Not Resolved -),			
										Nausea (n/a - Not Recovered/Not Resolved -), Somnolence (n/a -			
										Not Recovered/Not Resolved -), Vaccination site pain			
										(3d - Recovered/Resolved -), Vaccination site rash			
EU-EC-	22/12/2021	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Male	No	(1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011046268	, <i></i> , -0/-1	-po-italicous	Professional		sc cronuste	Years	. asiastelli	. MC		Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown -	(S - n/a - n/a - [n/a - n/a - n/a - Intramuscular])	sc reported	1000
EU 50	22/12/2	C	Na	N.	Not as 1911	40 :-	No.	F		Other Medically Important Condition)	COMIDNITY	Not	
EU-EC- 10011046334	22/12/2021	Spontaneous		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 - n/a])	Not reported	ICSR

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											Dizziness (n/a - Unknown - Other Medically Important Condition),			
											Mobility decreased (n/a - Unknown - Other Medically Important Condition),			
											Pain in extremity (n/a - Not Recovered/Not Resolved - Other			
											Medically Important Condition), Pyrexia (n/a - Not Recovered/Not			
											Resolved - Other Medically Important Condition)			
	EU-EC- 10011046342	22/12/2021	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	<u>ICSR</u>
					Area						Fatigue (n/a - Not Recovered/Not Resolved - Disabling),	n/a])		
											Headache (n/a - Not Recovered/Not Resolved - Disabling),			
											Nausea (n/a - Not Recovered/Not Resolved - Disabling),			
	FILEO	22/42/2024		N	No.	No. of the	12.17	Not	Fl.		Pain (n/a - Recovering/Resolving - Disabling)	COMPANY (TOTAL MED AV	TANELLIENZA MEDICA	1000
	EU-EC- 10011046375	22/12/2021	Spontaneous	Healthcare Professional	European	Not available	12-17 Years	Not Specified	Female		Abdominal pain upper (13d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		<u>ICSR</u>
											Chest pain (4d - Recovered/Resolved - Other Medically Important Condition),			
											Chills (2d - Recovered/Resolved - Other Medically Important Condition),			
											Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Fatigue (n/a - Unknown - Other Medically Important Condition),			
											Nausea (5d - Recovered/Resolved - Other Medically Important Condition),			
											Oropharyngeal pain (6d - Recovered/Resolved - Other Medically Important Condition),			
											Pain (6d - Recovered/Resolved - Other Medically Important Condition)			
	EU-EC- 10011046428	22/12/2021	Spontaneous	Healthcare Professional	European	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 - [n/a - n/a - n/a])	Not reported	ICSR
											Cold sweat (n/a - Unknown - Other Medically Important Condition),			
											Fatigue (n/a - Unknown - Other Medically Important Condition),			
											Feeling hot (n/a - Unknown - Other Medically Important Condition),			
											Malaise (n/a - Unknown - Other Medically Important Condition),			

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										Myocarditis (n/a - Unknown - Other Medically Important Condition),			
										Pain (n/a - Unknown - Other Medically Important Condition),			
										Pericarditis (n/a - Unknown - Other Medically Important Condition),			
										Pyrexia (n/a - Unknown - Other Medically Important Condition),			
										Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important			
	EU-EC- L0011046434	22/12/2021		Healthcare Professional	Non European Economic Area	Not available	Not Specified	Male	No	upper (1d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	ADALIMUMAB [ADALIMUMAB] (C - Crohn's disease - n/a - [n/a - n/a - n/a]),	ICSR
										Condition), Decreased appetite (n/a - Not Recovered/Not		AZATHIOPRINE [AZATHIOPRINE] (C - Crohn's disease - n/a - [332d - n/a - n/a]),	
										Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not		[INFLUENZA VIRUS] (C - Immunisation - n/a - [1d - n/a - n/a])	
										Recovered/Not Resolved - Other Medically Important Condition),			
										Immunisation (n/a - Unknown - Other Medically Important Condition),			
										Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
	EU-EC- 10011046455	22/12/2021	Spontaneous	Professional	European Economic	Not available	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a -	Not reported	<u>ICSR</u>
					Area					Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition),	n/a])		
										Tachycardia (n/a - Recovering/Resolving -)			
	EU-EC- 10011046594	22/12/2021	Spontaneous	Professional		Not available	Not Specified	Female		Abdominal pain upper (n/a - Unknown - Other Medically Important Condition),	FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]	Not reported	ICSR
										Arthralgia (n/a - Unknown - Other Medically Important Condition),	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
										Injection site reaction (n/a - Unknown - Other Medically Important Condition),			
										Myalgia (n/a - Unknown - Other Medically Important Condition),			
										Oedema peripheral (n/a - Unknown - Other Medically Important Condition),			
										Rash morbilliform (n/a - Unknown - Other Medically Important Condition),			
										Urticaria (n/a - Unknown - Other Medically Important Condition)			
	EU-EC- 10011047305	22/12/2021	Spontaneous	Professional	European Economic	Not available	Not Specified	Female	No	Pruritus (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
					Area					Rash pruritic (n/a - Recovering/Resolving	Intramuscular])		
- 1										-),			

										- Other Medically Important Condition)			
EU-EC- 10011047306	22/12/2021	Spontaneous		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- 10011047310	22/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Appendicitis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011047311	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (2min Recovered/Resolved - Other Medically Important Condition), Vision blurred (2min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011047313	22/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (15min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011047314	22/12/2021	Spontaneous	Non Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nephrotic syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Oedema peripheral (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Periorbital oedema (n/a - Recovered/Resolved - Caused/Prolonged			
										Hospitalisation), Swelling face (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011047317	22/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (10min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011047322	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nasopharyngitis (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011047328	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Important Condition) Syncope (5min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011047338	22/12/2021	Spontaneous	Healthcare	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011047339	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Important Condition) Chills (n/a - Unknown -), Headache (n/a - Unknown -), Nausea (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -), Syncope (n/a - Unknown - Other Medically Important Condition), Vaccination site	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	22/12/2021	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	hypoaesthesia (n/a - Unknown -) Chills (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

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10011047340			Healthcare Professional	European Economic Area		Years	Specified			Recovered/Resolved - Caused/Prolonged Hospitalisation),	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
										Dehydration (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Feeling of body temperature change			
										(n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Influenza like illness (n/a -			
										Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Lethargy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),			
										Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC- 10011047358	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bradycardia (8min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Dizziness (n/a - Recovered/Resolved -),			
										Pallor (8min - Recovered/Resolved -)			
EU-EC- 10011047364	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011047366	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (10min - 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- 10011047371	22/12/2021	Spontaneous	Non Healthcare Professional	Non European	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- 10011047373	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ischaemic stroke (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Transient ischaemic attack (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011047376	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Appendicitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC- 10011047379	22/12/2021	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
EU-EC- 10011047388	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a -	Not reported	ICSR
EU-EC- 10011047451	22/12/2021	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										Eye irritation (n/a - Not Recovered/Not Resolved - Disabling),		[ZOLPIDEM, ZOLPIDEM TARTRATE] (C - n/a -	
										Eye pain (n/a - Not Recovered/Not Resolved - Disabling),		n/a - [n/a - n/a - n/a])	
										Fatigue (n/a - Not Recovered/Not Resolved - Disabling),			

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										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Disabling),			
										Migraine (n/a - Not Recovered/Not Resolved - Disabling),			
										Myalgia (n/a - Not Recovered/Not Resolved - Disabling),			
										Pyrexia (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC- 10011047462	22/12/2021	Spontaneous	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 - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011047493	22/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Grip strength decreased (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
										Illusion (n/a - Not Recovered/Not Resolved -),			
										Limb discomfort (n/a - Not Recovered/Not Resolved -), Movement disorder			
										(n/a - Not Recovered/Not Resolved -), Neuropathy			
										peripheral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC- 10011047519	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
										Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),			
										Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011047521	22/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	-), Electrocardiogram	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	<u>ICSR</u>
										normal (n/a - Recovered/Resolved -), Pericarditis (n/a -			
										Recovered/Resolved - Other Medically Important Condition),			
										Troponin increased (n/a - Recovered/Resolved -)			
EU-EC- 10011047551	22/12/2021	Spontaneous	Professional		Not available	12-17 Years	Not Specified	Male	No	Nasopharyngitis (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Overdose (n/a - Unknown -), Product preparation error (n/a - Unknown			
										-), Pyrexia (n/a - Recovered/Resolved -)			
EU-EC- 10011047608	22/12/2021	Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
										Chest pain (n/a - Recovering/Resolving - Other Medically Important	<u> </u>	[FISH OIL] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically		[GUANFACINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	
										Important Condition), Fatigue (n/a -		[LAMOTRIGINE] (C - Depression - n/a - [n/a - 25mg - n/a]),	

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											Recovering/Resolving - Other Medically Important Condition), Feeding disorder (n/a - Recovering/Resolving - Other Medically Important Condition), Hypertension (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition), Weight decreased (n/a - Recovering/Resolving - Other Medically Important Condition),		[NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE, SERTRALINE, SERTRALINE, SERTRALINE, SERTRALINE, SERTRALINE, SERTRALINE, SERTRALINE, SIBORDAN, SERTRALINE, SER	
											- Other Medically Important Condition)			
	EU-EC- 10011047637	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	[ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID] (C - n/a - n/a - [n/a -	ICSR
											Resolved -), Heart rate increased (n/a - Not Recovered/Not Resolved - Other Medically Important		n/a - n/a]), [FERROUS BISGLYCINATE] (C - n/a - n/a - [n/a - n/a - n/a]),	
											Condition), Oropharyngeal pain (n/a - Not		[LEVOMEFOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]),	
											Recovered/Not Resolved -),		[MECOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a]),	
											Pyrexia (n/a - Not Recovered/Not Resolved -)		[PYRIDOXAL PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a -	
	EU-EC- 10011047718	22/12/2021	Spontaneous		Economic	Not available	12-17 Years	Not Specified	Female	No		COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	n/a])	ICSR
											Anosmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
											Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition),			
											Headache (n/a - Recovering/Resolving - Other Medically Important Condition)			
	EU-EC- 10011047742	22/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	<u>ICSR</u>
	EU-EC- 10011047780	22/12/2021	Spontaneous	Non	Non European	Not available	12-17 Years	Not Specified	Male	No	Acute disseminated encephalomyelitis	TOZINAMERAN [TOZINAMERAN] (S - COVID-	Not reported	ICSR
	1001107//00				Economic Area		icais	эрсипеи			(n/a - Unknown - Other Medically Important Condition),	19 immunisation - Not applicable - [1d - n/a - n/a])		
											Aphasia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Gait inability (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),			
											Neurological decompensation (n/a - Not Recovered/Not Resolved - Other			
											Medically Important			

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										Condition), Psychomotor skills impaired (n/a - Not Recovered/Not Resolved -), Wheelchair user (n/a - Not Recovered/Not Resolved - Other			
EU-EC- 10011047801	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Medically Important Condition) C-reactive protein increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a])	CYMBALTA [DULOXETINE, DULOXETINE HYDROCHLORIDE] (C - Depression - n/a -	ICSR
										Hospitalisation), Colitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged		[n/a - n/a - Oral]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE, SODIUM SESQUIHYDRATE] (C - Gastrooesophageal reflux disease - n/a - [n/a - n/a - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MALEATE, AMLODIPINE MOSILATE, AMLODIPINE MOSILATE, AMLODIPINE MOSILATE, AMLODIPINE MOSILATE, AMLODIPINE MOSILATE, AMLODIPINE MOSILATE, AMLODIPINE MOSILATE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [METOPROLOL, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - n/a - Oral]),	
										Hospitalisation), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)		[VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC- 10011047836	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 immunisation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC- 10011047867	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Not Specified	Female	No	-), Pyrexia (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSF
EU-EC- 10011047968	22/12/2021	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	ICSF
EU-EC- 10011048061	22/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Adolescent	Male	No	Important Condition) Abdominal pain (n/a Recovered/Resolved -), Ageusia (n/a - Recovered/Resolved -), Chills (n/a -	Intramuscular]) (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),			
										Lymphadenopathy (n/a - Unknown -), Nausea (n/a - Recovered/Resolved			
										-), Pyrexia (n/a - Recovered/Resolved			
EU-EC- 10011048210	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Immunisation reaction (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
tns://dan.e		na aulana	hutiaa/aayu	dii3Ca						Thrombocytopenia			58/6

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										(n/a - Unknown - Other Medically Important Condition)			
EU-EC- 10011048227	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (555min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011048389	22/12/2021	Spontaneous	Healthcare	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (1wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICS
EU-EC- 10011048457	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
EU-EC- 10011048487	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown -), Headache (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), INFLECTRA [INFLIXIMAB] (S - Juvenile idiopathic arthritis - Unknown - [n/a - 250mg - n/a])	ARAVA [LEFLUNOMIDE] (C - Juvenile idiopathic arthritis - n/a - [n/a - 20mg - n/a])	ICS
EU-EC- 10011048508	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
EU-EC- 10011048510	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Chua, G Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination. 2021	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myopericarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICS
										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC- 10011048726	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (9d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICS
EU-EC- 10011048796	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Resolved - Other Medically Important	Not applicable - [1d - n/a -	[ULIPRISTAL ACETATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Depression - n/a -	ICS
										Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatique (n/a -		[n/a - n/a - n/a])	
										Unknown - Other Medically Important Condition), Headache (n/a - Not			
										Recovered/Not Resolved - Other Medically Important Condition),			
										Immunisation (n/a - Unknown - Other Medically Important Condition),			
										Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Palpitations (n/a - Unknown - Other Medically Important Condition),			
FILE C	22/42/2	Control	112.12	N-	Note to the second	10.15	NI=:		l l	Tachycardia (n/a - Unknown - Other Medically Important Condition)	COMPNIATOR	Not as a six	
10011049004		Spontaneous	Professional	Non European Economic Area	Not available	12-17 Years	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])	inot reported	ICS
EU-EC- 10011049427	22/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSF

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				Economic Area						Recovered/Resolved - Other Medically Important Condition)	Not applicable - [1d - n/a - Intramuscular])		
EU-EC- 10011049624	22/12/2021	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	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICS
										- Other Medically Important Condition)			
EU-EC- 10011049901	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (57d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSF
EU-EC- 10011050013	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anaemia (n/a - Recovering/Resolving -), Heavy menstrual	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSF
										bleeding (n/a - Recovering/Resolving -)			
EU-EC- 10011050059	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
										Important Condition)			
EU-EC- 10011050144	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	<u>ICSR</u>
EU-EC- 10011050148	22/12/2021	Spontaneous		European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Unknown -), Pyrexia (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
										Vomiting (n/a -			
EU-EC- 10011050156		Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Unknown -) Condition aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSF
										Influenza (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Post viral fatigue syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important			
										Condition), Sleep disorder (n/a - Not Recovered/Not Resolved - Other Medically Important			
	22/12/222/			_		10.10				Condition)			
EU-EC- 10011050160	22/12/2021	Spontaneous	Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (63d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC- 10011050162	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epididymitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
										Testicular pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),			
										Testicular swelling (n/a - Not Recovered/Not Resolved - Other Medically Important			
EU-EC- 10011050447	22/12/2021	Spontaneous		European Economic	Not available	12-17 Years	Not Specified	Male	No	Condition) Cough (n/a - Not Recovered/Not Resolved - Other	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
			Professional	Alea						Medically Important Condition), Fatigue (n/a -			
EU-EC-	22/12/2021	Coortes	Non	Non	Not available	12.17	Not	Eoma!-	No	Unknown - Other Medically Important Condition)	COMIDNATY (TOZINAMEDAN)	ARAVA	ICCO
10011050556	22/12/2021	Spontaneous		Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Unknown -), Dizziness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]),	[LEFLUNOMIDE] (C - Juvenile idiopathic arthritis - n/a - [n/a - 20mg - n/a])	ICSR
										Fatigue (n/a - Unknown -),	INFLECTRA [INFLIXIMAB] (S - Juvenile idiopathic arthritis - Drug withdrawn - [1107d - 250mg - n/a])	5 ',,~1,	
										Headache (n/a - Unknown -), Multiple sclerosis			
										(n/a - Unknown - Caused/Prolonged			

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										Hospitalisation, Other Medically Important Condition),			
										Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),			
										Quadriparesis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)			
EU-EC- 10011019548	21/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Asthenia (1d - Recovered/Resolved -), Mydriasis (1d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular])	Not reported	ICSR
										Recovered/Resolved -), Somnolence (1d - Recovered/Resolved -),			
										Visual impairment (1d - Recovered/Resolved -)			
EU-EC- 10011019662	21/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Immunisation reaction (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	<u>ICSR</u>
EU-EC- 10011019663		Spontaneous	Professional	Area	Not available	Years	Not Specified	Female	No	Malaise (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	, 	ICSR
EU-EC- 10011020000	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Polymenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC- 10011020159	21/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Not Specified	No	Rash (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	<u>ICSR</u>
EU-EC- 10011020229	21/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Headache (9d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Loss of consciousness (9d - Recovered/Resolved - Other Medically Important Condition),			
										Pain in extremity (9d - Recovered/Resolved			
										- Other Medically Important Condition),			
										Paraesthesia (9d - Recovered/Resolved - Other Medically Important Condition),			
										Seizure (9d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC- 10011020234	21/12/2021	Spontaneous	Non Healthcare Professional	Economic	Not available	12-17 Years	Not Specified	Female	No	Dermatitis atopic (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC- 10011020260	21/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Female	No	Chest pain (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular])	Not reported	ICSR
										Headache (4d - Recovered/Resolved -),			
										Pyrexia (4d - Recovered/Resolved -),			
EU-EC-	21/12/2021	Spontaneous	Healthcare	European	Not available	12-17	Not	Male	No	Rash (4d - Recovered/Resolved -) Fatigue (4d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011020282			Professional			Years	Specified			Recovered/Resolved -), Feeling cold (4d - Recovered/Resolved	(S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
										-), Pain in extremity (4d			
EU-EC-	21/12/2021	Spontaneous	Healthcaro	Furonean	Not available	12-17	Not	Female	No	Recovered/Resolved -) Fatigue (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR
10011020359	21,12,2021	Sportaneous	Professional		available		Specified	Smale	"		(S - COVID-19 immunisation -	oc reported	אנטנ

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				Area							n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC- 10011020413	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - η/a - [n/a - 3.mL - Intramuscular])	Not reported	ICSR
EU-EC- 10011020536	21/12/2021	Spontaneous	Healthcare Professional		Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved -), Bone pain (n/a - Recovered/Resolved -), Peripheral swelling (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - η/a - [η/a - 1{OF} - Intramuscular])	Not reported	ICSR

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