Individual Case Safety Report Form

General Information EudraVigilance Local Report Number		illulvidual Case Salei	y Keport i oriii		Eddia vigilarioo	
Sender Type Health professional Sender's Organisation PFIZER S.R.L. Type of Report Spontaneous Primary source country Non-European Economic Area Reporter's qualification Healthcare Professional Case serious? Yes Patient Age Group Age Group (as per reporter) Sex 12-17 Years Female Reaction / Event MedDRA LLT Duration Outcome Seriousness¹ Seizure Fatal death. Difficulty breathing Fatal death. Drug Information Role² Drug Duration Dose Units in Interval Action taken	General Information					
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Difficulty breathing Fatal death. Drug Information Role² Drug Duration Dose Units in Interval Action taken	MedDRA LLT	Duration	Out	tcome	Seriousness ¹	
Drug Information Role² Drug Duration Dose Units in Interval Action taken	Seizure		F	atal	death.	
Role ² Drug Duration Dose Units in Interval Action taken	Difficulty breathing		F	atal	death.	
	Drug Information					
	Role ² Drug	Duration	Dose	Units in Interval	Action taken	
S COMIRNATY - TOZINAMERAN 1.0 Days Total Not applicable	S COMIRNATY - TOZINAMERAN	1.0 Days		Total	Not applicable	
Drug Information (cont.)	Drug Information (cont.)					
Info ³ Drug Indication Pharm. Form Route of Admin.	Info ³ Drug	Indicati	on	Pharm. Form	Route of Admin.	
COMIRNATY - TOZINAMERAN COVID-19 immunization Intramuscular use	COMIRNATY - TOZINAMERAN	COVID-19 imm	unization		Intramuscular use	

Seriousness: death=results in death; life threat.=life threatening; hospital.=requires hospitalization/prolongation of hospitalization; disability=results in disability/incapacity; congen.=congenital anomaly/birth defect; other=other medically important information; (blank)=non-serious

² Drug role: S=suspect; C=concomitant; I=interacting; N=not administered

³ Additional Information on Drug: 1=Counterfeit; 2= Overdose; 3=Drug taken by the father; 4=Drug taken beyond expiry date; 5=Batch and lot tested and found within specifications; 6=Batch and lot tested and found not within specifications; 7=Medication error; 8=Misuse; 9=Abuse; 10=Occupational exposure; 11=Off label use; (blank) = no additional information