EVPM ICSR(s)	Individual Case Safety Report Form			EudraVigilance	
General Information					
EudraVigilance Local Report Number	EU-EC-10010963145	EU-EC-10010963145			
Sender Type	Health professional	Health professional			
Sender's Organisation	PFIZER S.R.L.	PFIZER S.R.L.			
Type of Report	Spontaneous	Spontaneous			
Primary source country	Non-European Economic Area				
Reporter's qualification	Non-Healthcare Professional	Non-Healthcare Professional			
Case serious?	Yes				
Patient					
Age Group	Age Group (as	Age Group (as per reporter)		Sex	
12-17 Years					
Reaction / Event					
MedDRA LLT	Duration		Outcome	Seriousness ¹	
Accident		Fatal		death.	
Drug Information					
Role ² Drug	Duration	Dose	Units in Interv	al Action taken	
S COMIRNATY - TOZINAMERAN			Total	Not applicable	
Drug Information (cont.)					
Info ³ Drug	Indicatio	n	Pharm. Form	Route of Admin.	
COMIRNATY - TOZINAMERAN	COVID-19 imm	unisation			

¹ 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