EVPM ICSR(s)	Individual Case Safety Report Form				EudraVigilance	
General Information						
EudraVigilance Local Report Number	EU-EC-10010672595	EU-EC-10010672595				
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 Profes	Non-Healthcare Professional				
Case serious?	Yes	Yes				
Patient						
Age Group	Age Group (as per reporter)			Sex		
12-17 Years			Female			
Reaction / Event						
MedDRA LLT	Duration	Duration Outo			Seriousness ¹	
Pulmonary embolism		Fata			death.	
Drug Information						
Role ² Drug	Duration	Dose	Units in In	erval	Action taken	
S COMIRNATY - TOZINAMERAN	1.0 Days		Total		Not applicable	
Drug Information (cont.)						
Info ³ Drug	Inc	lication	Pharm. For	n	Route of Admin.	
COMIRNATY - TOZINAMERAN	COVID-1	COVID-19 immunisation				

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