Individual Case Safety Report Form

EVPINITOSK(S)			individual Case Safety Report Form				Eudravigilarice	
General Information								
EudraVigilance Local Report Number		EU-E0	EU-EC-10010988637					
Sender Type		Health	Health professional					
Sender's Organisation		PFIZE	PFIZER S.R.L.					
Type of Report		Spont	Spontaneous					
Primary source country		Non-E	Non-European Economic Area					
Reporter's qualification		Non-H	Non-Healthcare Professional					
Case serious?		Yes						
Patient								
Age Group			Age Group (as per reporter)				Sex	
12-17 Years							Female	
Reaction / Event								
MedDRA LLT			Duration		Outcome		Seriousness ¹	
Clotting disorder				Fatal			death.	
Dizzy				Fatal			death., hospital.	
Anaphylactic shock				Fatal			death., hospital.	
Rash				Fatal			death., hospital.	
Drug In	formation							
Role ²	Drug		Duration	Dose		Units in Interval	Action taken	
S COMIRNATY - TOZINAMERAN			1.0 Days	Total		Total	Not applicable	
Drug Information (cont.)								
Info ³	Info ³ Drug		Indication			harm. Form	Route of Admin.	
COMIRNATY - TOZINAMERAN			COVID-19 immunisation					

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

 $^{2 \}quad \text{Drug role: } \textbf{S} \text{=-suspect; } \textbf{C} \text{=-concomitant; } \textbf{I} \text{=-interacting; } \textbf{N} \text{=-not administered}$

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