Individual Case Safety Report Form

EVPIVITOSK(S)			individual Case Safety Report Form				Eudravigilarice	
Genera	I Information							
EudraVigilance Local Report Number		EU-E	EU-EC-10010994802					
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		Healthcare Professional						
Case serious?		Yes						
Patient								
Age Group		Age Group (as per reporter)				Sex		
12-17 Years							Male	
Reaction	on / Event							
MedDRA LLT			Duration		Outcome		Seriousness ¹	
Malaise				Unknown				
Completed suicide				Fatal			death., other	
Nasal congestion			Unknown					
Drug In	formation							
Role ²	Drug		Duration	Dose	T I	Units in Interval	Action taken	
S	COMIRNATY - TOZINAMERAN		1.0 Days			Total	Not applicable	
Drug In	formation (cont.)							
Info³ Drug COMIRNATY - TOZINAMERAN			Indication		Pharm. Form		Route of Admin.	
			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

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

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