Individual Case Safety Report Form

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General Information								
EudraVigilance Local Report Number			EU-EC-10010868257					
Sender Type		Health	Health professional					
Sender's Organisation			PFIZER S.R.L.					
Type of Report			Spontaneous					
Primary source country			European Economic Area					
Reporter's qualification			Non-Healthcare Professional					
Case serious?			Yes					
Patient								
Age Group			Age Group (as per reporter)			Sex		
12-17 Years							Male	
Reaction / Event								
MedDRA LLT			Duration		Outcome		Seriousness ¹	
Sudden death, cause unknown				Fatal			death., other	
Drug Information								
Role ²	Drug		Duration	Dose		Units in Interval	Action taken	
S	COMIRNATY - TOZINAMERAN					Total	Not applicable	
Drug Information (cont.)								
Info ³	Info³ 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