Individual Case Safety Report Form

LVI W IOOK(3)	individual Case Salety Report Form					Ludiavigilarioo	
General Information							
EudraVigilance Local Report Number	EU-EC-10014311323						
Sender Type	Health	Health professional					
Sender's Organisation	PFIZER S.R.L.						
Type of Report	Spontaneous						
Primary source country	Non-European Economic Area						
Reporter's qualification	Healthcare Professional						
Case serious?	Yes						
Patient							
Age Group		Age Group (as p	er reporter)	reporter)		Sex	
12-17 Years						Male	
Reaction / Event							
MedDRA LLT	Duration			Outcome		Seriousness ¹	
Joint pain				Fatal		death.	
Dyspnea			Fatal			death.	
Drug Information							
Role ² Drug		Duration	Dose	T I	Units in Interval	Action taken	
S COMIRNATY - TOZINAMERAN		1.0 Days			Total	Not applicable	
Drug Information (cont.)							
Info ³ Drug	Indication			Pharm. Form		Route of Admin.	
COMIRNATY - TOZINAMERAN	COVID-19 immunis		nisation	ation Solution for injection		Intramuscular use	

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