EVPM ICSR(s)	Individual Case Safety Report Form					EudraVigilance	
General Information							
EudraVigilance Local Report Number	EU-E	EU-EC-10010820898					
Sender Type	Healt	Health professional					
Sender's Organisation	PFIZE	PFIZER S.R.L.					
Type of Report	Spont	Spontaneous					
Primary source country	Europ	European Economic Area					
Reporter's qualification	Healt	Healthcare Professional					
Case serious?	Yes	Yes					
Patient							
Age Group		Age Group (as per reporter)			Sex		
		Child					
Reaction / Event							
MedDRA LLT		Duration		Outcome		Seriousness ¹	
Myocarditis				Unknown		other	
Inappropriate age at vaccine administration		1		Unknown			
Drug Information							
Role ² Drug		Duration	Dose		Units in Interval	Action taken	
S COMIRNATY - TOZINAMERAN					Total	Not applicable	
Drug Information (cont.)							
Info ³ Drug		Indication		Pharm. Forr		Route of Admin.	
COMIRNATY - TOZINAMERAN		COVID-19 immuni				Intramuscular use	

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