EVPM ICSR(s)	Individual Case Safety Report Form					EudraVigilance
General Information						
EudraVigilance Local Report Number	EU-EC-10010093581					
Sender Type	Health professional					
Sender's Organisation	PFIZER S.R.L.					
Type of Report	Spontaneous					
Primary source country	European Economic Area					
Reporter's qualification	Healthcare Professional					
Case serious?	Yes					
Patient						
Age Group		Age Group (as p	er reporter)	Sex		
	Child					
Reaction / Event						
MedDRA LLT	Duration		Outcome			Seriousness <sup>1</sup>
Myocarditis			Unknown			other
Inappropriate age at vaccine administration				Unknown		
Drug Information						
Role <sup>2</sup> Drug		Duration	Dose	U	nits in Interval	Action taken
S COMIRNATY - TOZINAMERAN					Total	Not applicable
Drug Information (cont.)						
Info³ Drug	Indication			Pharm. Form		Route of Admin.
COMIRNATY - TOZINAMERAN	COVID-19 immunis		nisation			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

<sup>2</sup> Drug role: S=suspect; C=concomitant; I=interacting; N=not administered

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