EVPM ICSR(s)	Individual Case Safety Report Form				EudraVigilance	
General Information						
EudraVigilance Local Report Number	EU-EC-10010986554	EU-EC-10010986554				
Sender Type	Health professional	Health professional				
Sender's Organisation	PFIZER S.R.L.	PFIZER S.R.L.				
Type of Report	Spontaneous	Spontaneous				
Primary source country	Non-European Economic Area					
Reporter's qualification	Healthcare Professional	Healthcare Professional				
Case serious?	Yes					
Patient						
Age Group	Age Group (a	Age Group (as per reporter)		Sex		
3-11 Years						
Reaction / Event						
MedDRA LLT	Duration		Outcome		Seriousness <sup>1</sup>	
Unknown cause of death			Fatal		death.	
Drug Information						
Role <sup>2</sup> Drug	Duration	Dose	L 1	Jnits in Interval	Action taken	
S TOZINAMERAN - TOZINAMERAN				Total	Not applicable	
Drug Information (cont.)						
Info <sup>3</sup> Drug	Indica	tion	Pharm. Form		Route of Admin.	
TOZINAMERAN - TOZINAMERAN	COVID-19 im	COVID-19 immunization				

<sup>1</sup> 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

<sup>3</sup> 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