General Information

EudraVigilance Local Report Number	EU-EC-10009668305
Sender Type	Health professional
Sender's Organisation	NATIONAL AGENCY FOR THE SAFETY OF MEDICINE AND HEALTH PRODUCTS
Type of Report	Spontaneous
Primary source country	European Economic Area
Reporter's qualification	Healthcare Professional
Case serious?	Yes

Patient

Age Group	Age Group (as per reporter)	Sex
12-17 Years	Adolescent	Female

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness[1]
Cardiac arrest	1.0 Days	Fatal	death., life threat.

Drug Information

Role[2]	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN	1.0 Days	1.0 {DF}		Not applicable

Drug Information *(cont.)*

Info[3]	Drug	Indication	Pharm. Form	Route of Admin.
	COMIRNATY - TOZINAMERAN	COVID-19 vaccination		Intramuscular use

Rechallenge matrix table

Reaction/Event (MedDRA LLT)	Drug	Rechallenge? / Reaction recurred?
Cardiac arrest	COMIRNATY - TOZINAMERAN	no - n/a

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