Individual Case Safety Report Form

General Information

EudraVigilance Local Report Number	EU-EC-10010962033
Sender Type	Regulatory authority
Sender's Organisation	EEA Regulator
Type of Report	Spontaneous
Primary source country	European Economic Area
Reporter's qualification	Non-Healthcare Professional
Case serious?	Yes

Patient

Age Group	Age Group (as per reporter)	Sex
2 Months - 2 Years		Female

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness[1]
Allergic reaction		Not Recovered/Not Resolved	hospital., other

Drug Information

Role[2]	Drug	Duration	Dose	Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN				
C	IBRANCE 100 MG - PALBOCICLIB				

Drug Information *(cont.)*

Info[3]	Drug	Indication	Pharm. Form	Route of Admin.
	COMIRNATY - TOZINAMERAN	N/A		
	IBRANCE 100 MG - PALBOCICLIB	N/A		Oral 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