Individual Case Safety Report Form

General Information EudraVigilance Local Report Number EU-EC-10008410508 Sender Type Health professional Sender's Organisation PFIZER S.R.L. Type of Report Spontaneous Primary source country Non-European Economic Area Reporter's qualification Non-Healthcare Professional Case serious? Yes Patient Sex Age Group Female Reaction / Event MedDRA LLT **Duration** Outcome Seriousness¹ Inappropriate age at vaccine administration Unknown Unknown cause of death Fatal death. **Drug Information** Role² Drug **Duration** Dose **Units in Interval** Action taken 1.0 Days S TOZINAMERAN - TOZINAMERAN Not applicable Total Drug Information (cont.) Info³ Drug Indication Pharm. Form Route of Admin. TOZINAMERAN - TOZINAMERAN COVID-19 immunisation

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