Individual Case Safety Report Form

General Information EudraVigilance Local Report Number EU-EC-10009749988 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 Sex Female Reaction / Event MedDRA LLT **Duration** Outcome Seriousness¹ Arrhythmia Fatal death. **Drug Information** Role² Duration Dose **Units in Interval** Action taken COMIRNATY - TOZINAMERAN Total Not applicable Drug Information (cont.) Info³ Drug Pharm. Form Route of Admin. Indication COMIRNATY - 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