## **Individual Case Safety Report Form**

individual case Salety Report 1 of in							Eddiavigilarioo	
General Information								
EudraVigilance Local Report Number		EU-E	EU-EC-10012414277					
Sender Type		Regul	Regulatory authority					
Sender's Organisation		EEA F	EEA Regulator					
Type of Report		Spont	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		
18-64 Years							Male	
Reaction / Event								
MedDRA LLT		Duration		Outcome		ne	Seriousness <sup>1</sup>	
Death			0.0 Days		Fatal		death.	
Drug ineffective			21.0 Days	Fatal			death., hospital., other	
Drug Information								
Role <sup>2</sup> D	rug		Duration	Dose		Units in Interval	Action taken	
S C	OMIRNATY - TOZINAMERAN							
Drug Information (cont.)								
Info <sup>3</sup> Dr	Info³ Drug		Indication		Pharm. Form		Route of Admin.	
COMIRNATY - TOZINAMERAN			N/A					

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