## **Individual Case Safety Report Form**

General Information								
EudraVigilance Local Report Number			EU-EC-10012996882					
Sender Type		Regul	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		
65-85 Years						Female		
Reaction / Event								
MedDRA LLT		Duration		Outcome		me	Seriousness <sup>1</sup>	
Haemoptysis			164.0 Days		Fatal		death., hospital., other	
Drug In	formation							
Role <sup>2</sup>	Drug		Duration	Dose		Units in Interval	Action taken	
S	COMIRNATY - TOZINAMERAN							
Drug In	formation (cont.)							
Info <sup>3</sup>	Drug		Indication	cation		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

 $<sup>2 \</sup>quad \text{Drug role: } \textbf{S} \text{=-suspect; } \textbf{C} \text{=-concomitant; } \textbf{I} \text{=-interacting; } \textbf{N} \text{=-not administered}$ 

<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