EVPM ICSR(s)	Individual Case Safety Report Form					EudraVigilance
General Information						
EudraVigilance Local Report Number	EU-EC-10012949156					
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	
			Female			
Reaction / Event						
MedDRA LLT	Duration			Outcome		Seriousness ¹
Colorectal cancer				Unknown		life threat., other
Drug Information						
Role ² Drug		Duration	Dose	U	Jnits in Interval	Action taken
S COMIRNATY - TOZINAMERAN						
Drug Information (cont.)						
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

 $^{2 \}quad \text{Drug role: } \textbf{S} \text{=} \text{suspect; } \textbf{C} \text{=} \text{concomitant; } \textbf{I} \text{=} \text{interacting; } \textbf{N} \text{=} \text{not administered}$

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