Individual Case Safety Report Form

EVPM IC	3K(S)	individ	idividual Case Safety Report Form				EudraVigilance	
General Information								
EudraVigilance Local Report Number		EU-E0	EU-EC-10008053546					
Sender Type		Health	Health professional					
Sender's Organisation		PFIZE	PFIZER S.R.L.					
Type of Report		Spont	Spontaneous					
Primary source country		Europ	European Economic Area					
Reporter's qualification		Healthcare Professional						
Case serious?		Yes						
Patient								
Age			Age Group				Sex	
16 Years							Male	
Reaction / Event								
MedDRA LLT			Duration		Outcome		Seriousness ¹	
Numbness in leg			Not Recovered/No		Resolved			
Multiple sclerosis				Not Recovered/Not Resol			other	
Loss of sensation			Not Recovered/Not Resolved			Resolved		
Pain in leg			Not Recovered/Not Resolved			Resolved		
Drug Information								
Role ²	Drug	Duration		Dose U		Inits in Interval	Action taken	
S	S COMIRNATY - TOZINAMERAN		1.0 Days			Total	Not applicable	
Drug Information (cont.)								
Info ³ Drug			Indication		Pharm. Form		Route of Admin.	
COMIRNATY - TOZINAMERAN			COVID-19 immunisation					

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