EVPM ICSR(s)		Individual Case Safety Report Form				EudraVigilance	
General Information							
EudraVigilance Local Report Number		EU-EO	C-10012305824				
Sender Type		Health	n professional				
Sender's Organisation		PFIZE	PFIZER S.R.L.				
Type of Report		Spont	Spontaneous				
Primary source country			European Economic Area				
Reporter's qualification			Non-Healthcare Professional				
Case serious?			No				
Patient							
Age Group			Age Group (as per reporter)			Sex	
18-64 Years						Female	
Reaction / Event							
MedDRA LLT			Duration		Outcome		Seriousness <sup>1</sup>
Venous edema			Not		ot Recovered/Not Resolved		
Maternal exposure during pregnancy				Unknown		1	
Burning sensation			Not Recovered/Not R			t Resolved	
Numbness			Not Recovered/Not			t Resolved	
Drug In	formation						
Role <sup>2</sup>	Drug		Duration	Dose	- L	Jnits in Interval	Action taken
S	S COMIRNATY - TOZINAMERAN		1.0 Days			Total	Not applicable
Drug Information (cont.)							
Info <sup>3</sup>	Drug		Indication		Pharm. Form		Route of Admin.
	COMIRNATY - TOZINAMERAN		COVID-19 immur	COVID-19 immunization			Intramuscular use

<sup>1</sup> 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