Individual Case Safety Report Form

LVI W 100K(3)	individual Case Salety Report Form						
General Information							
EudraVigilance Local Report Number	EU-E	EU-EC-10011121872					
Sender Type	Healt	Health professional					
Sender's Organisation	PFIZ	PFIZER S.R.L.					
Type of Report	Spon	Spontaneous					
Primary source country	Non-	Non-European Economic Area					
Reporter's qualification	Non-	Non-Healthcare Professional					
Case serious?	Yes	Yes					
Patient							
Age Group		Age Group (as p	er reporter)	reporter)		Sex	
12-17 Years						Male	
Reaction / Event							
MedDRA LLT		Duration		Outcome		Seriousness ¹	
Tiredness				Fatal		death.	
Nerve damage				Fatal		death.	
Lung disorder				Fatal		death.	
Dizziness				Fatal		death., other	
Anemia				Fatal		death.	
Anaphylactic reaction			Fatal			death., other	
ck				Fatal		death., other	
normal stools				Fatal		death.	
Defecation disorder			Fatal			death., other	
Myocarditis				Fatal		death., other	
Abdominal pain			Fatal			death., other	
Breathing arrested				Fatal		death., other	
Vomited				Fatal		death.	
Drug Information							
Role ² Drug		Duration	Dose	U	nits in Interval	Action taken	
S COMIRNATY - TOZINAMERAN		1.0 Days			Total	Not applicable	
Drug Information (cont.)							
Info ³ Drug	Drug		Indication		arm. Form	Route of Admin.	
COMIRNATY - TOZINAMERAN	COMIRNATY - TOZINAMERAN		COVID-19 immunization				

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