## **Individual Case Safety Report Form**

EVPIVITCSR(S)	Individual Case Safety Report Form					Eudravigliance	
General Information							
EudraVigilance Local Report Number	EU-EC-10009033112						
Sender Type	Health professional						
Sender's Organisation	ASTRAZENECA PLC						
Type of Report	Spontaneous						
Primary source country	European Economic Area						
Reporter's qualification	Non-Healthcare Professional						
Case serious?	Yes						
Patient							
Age Group			Sex				
Adolescent			Female				
Reaction / Event							
MedDRA LLT	Duration		Outcome			Seriousness <sup>1</sup>	
Medication error			Fatal			death., other	
Product administered to patient of inappropriate age			Fatal			death., other	
Death			Fatal			death.	
Drug Information							
Role <sup>2</sup> Drug	Duration	ı .	Dose	Units i	n Interval	Action taken	
Drug Information (cont.)							
Info <sup>3</sup> Drug	In	dication		Pharm. Form		Route of Admin.	
Rechallenge matrix table							
Reaction/Event (MedDRA LLT)	Drug				Rechallenge? / Reaction recurred?		
Death	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)				no - n/a		
Medication error	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)				no - n/a		
Product administered to patient of inappropriate age	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)				yes - unk		

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