Individual Case Safety Report Form

EVPIVITCSR(S)			individual Case Safety Report Form				Eudravigilance	
General Information								
EudraVigilance Local Report Number		EU-E	EU-EC-10016958202					
Sender Type		Health	Health professional					
Sender's Organisation		ASTRAZENECA AB						
Type of Report		Spont	Spontaneous					
Primary source country		Non-European Economic Area						
Reporter's qualification		Non-Healthcare Professional						
Case serious?		Yes						
Patient								
Age Group			Age Group (as per reporter)			Sex		
Reaction	on / Event							
MedDRA LLT		Duration			Outcome		Seriousness ¹	
Vaccination adverse reaction			Fatal		Fatal		death.	
Drug Ir	nformation							
Role ²	Drug		Duration	Dose	U	Inits in Interval	Action taken	
S	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)						Unknown	
Drug Ir	nformation (cont.)							
Info ³	Info ³ Drug		Indication Ph		arm. Form	Route of Admin.		
VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)			N/A			on for injection	Intramuscular use	
Rechal	lenge matrix table							
Reaction/Event (MedDRA LLT)			Drug			Rechallenge? / Reaction recurred?		
Vaccinati	ion adverse reaction		/AXZEVRIA - COVID-19 VACCINE ASTRAZENECA CHADOX1 NCOV-19)			no - 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

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

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