## **Individual Case Safety Report Form**

EVPM ICSR(s)	Individual Case Safety Report Form					EudraVigilance	
General Information							
EudraVigilance Local Report Number	EU-E	EU-EC-10012927237					
Sender Type	Regulatory authority						
Sender's Organisation	EEA I	Regulator					
Type of Report	Spon	Spontaneous					
Primary source country	Europ	European Economic Area					
Reporter's qualification	Healt	Healthcare Professional					
Case serious?	Yes	Yes					
Patient							
Age Group		Age Group (as per reporter)			Sex		
18-64 Years					Male		
Reaction / Event							
MedDRA LLT		Duration		Outcome		Seriousness <sup>1</sup>	
Fever		1.0 Days		Fatal		death., hospital.	
Cough		1.0 Days		Fatal		death., hospital.	
Coronary artery disease				Fatal		death.	
Cardiomyopathy				Fatal		death.	
Dyspnea	1.0 Days			Fatal		death., hospital.	
Cardiopulmonary arrest		0.0 Days		Fatal		death.	
Death		0.0 Days		Fatal		death.	
Drug Information							
Role <sup>2</sup> Drug		Duration	Dose		Units in Interval	Action taken	
S VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19	)						
Drug Information (cont.)							
Info <sup>3</sup> Drug		Indication		Pharm. Form		Route of Admin.	
VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)	COVID-19 immun		nisation				

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