EVPM ICSR(s)		Individual Case Safety Report Form					EudraVigilance
General Information							
EudraVigilance Local Report Number			EU-EC-10016890517				
Sender Type		Healt	h professional				
Sender's Organisation		ASTR	ASTRAZENECA AB				
Type of Report		Spon	Spontaneous				
Primary source country			Non-European Economic Area				
Reporter's qualification		Non-I	Non-Healthcare Professional				
Case serious?		Yes					
Patient							
Age Group			Age Group (as per reporter)			Sex	
Reaction / Event							
MedDRA LLT		Duration		Outcome			Seriousness <sup>1</sup>
Vaccination adverse reaction					Fatal		death.
Drug Information							
Role <sup>2</sup>	Drug		Duration	Dose	U	nits in Interval	Action taken
S	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)						Unknown
Drug Information (cont.)							
Info <sup>3</sup>	Drug	Indication		Pharm. Form		arm. Form	Route of Admin.
	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)		N/A		Solution for injection		Intramuscular use
Rechallenge matrix table							
Reaction/Event (MedDRA LLT)			Drug			Rechallenge? / Reaction recurred?	
Vaccinati	ion adverse reaction		AXZEVRIA - COVID-19 VACCINE ASTRAZENECA HADOX1 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 1

<sup>2</sup> Drug role: S=suspect; C=concomitant; I=interacting; N=not administered

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