Individual Case Safety Report Form

individual Case Salety Report Form						Eddiavigilarioo
al Information						
ilance Local Report Number	EU-EC-10016890523					
ype	Health professional					
Organisation	ASTRAZENECA AB					
Report	Spontaneous					
source country	Non-European Economic Area					
s qualification	Non-F	Non-Healthcare Professional				
ious?	Yes					
Age Group		Age Group (as p	per reporter)		Sex	
on / Event						
LLT		Duration		Outcome		Seriousness ¹
on adverse reaction				Fatal		death.
formation						
Drug		Duration	Dose	U	Jnits in Interval	Action taken
VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19))					Unknown
formation (cont.)						
Drug	Indication		1	Pharm. Form		Route of Admin.
VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)	N/A			Solution for injection		Intramuscular use
lenge matrix table						
Reaction/Event (MedDRA LLT)		Drug		Rechalleng		nge? / Reaction recurred?
VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)					no - n/a	
	Idance Local Report Number lype Organisation Report Ource country Is qualification Ous? Age Group In / Event LLT On adverse reaction formation Drug VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) formation (cont.) Drug VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) enge matrix table Reaction/Event (MedDRA LLT)	I Information Ilance Local Report Number Ilance Local Report Ilance Local Report Il	Information Ilance Local Report Number Ilanch In Formation In Ilance Local Report Number Ilanch In Ilanch Ilanch In	Information Ilance Local Report Number Ilance Local Report Number Ilance In Ilance I	Information Idance Local Report Number Idance Local Repo	Information Ilance Local Report Number Ilance Local Repo

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