

General Information	
EudraVigilance Local Report Number	EU-EC-10011191214
Sender Type	Health professional
Sender's Organisation	MODERNA BIOTECH SPAIN S.L.
Type of Report	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
2 Months - 2 Years		Male

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness <sup>1</sup>
Transposition of the great vessels	176.0 Days	Fatal	death., congen., other
Tricuspid regurgitation		Not Recovered/Not Resolved	congen., other
Foetal exposure during pregnancy		Recovered/Resolved	

Drug Information					
Role <sup>2</sup>	Drug	Duration	Dose	Units in Interval	Action taken
S	SPIKEVAX - ELASOMERAN		1.0 {DF}		Drug withdrawn

Drug Information (cont.)					
Info <sup>3</sup>	Drug	Indication	Pharm. Form	Route of Admin.	Parent Route of Admin.
	SPIKEVAX - ELASOMERAN	COVID-19 vaccination		Transplacental	Intramuscular use

Rechallenge matrix table		
Reaction/Event (MedDRA LLT)	Drug	Rechallenge? / Reaction recurred?
Foetal exposure during pregnancy	SPIKEVAX - ELASOMERAN	no - n/a
Transposition of the great vessels	SPIKEVAX - ELASOMERAN	no - n/a
Tricuspid regurgitation	SPIKEVAX - ELASOMERAN	no - n/a

**Information Concerning the Parent for a Parent-Child/Foetus Report**

Parent	
Age	Sex
18-64 Years	Female

<sup>1</sup> 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