Individual Case Safety Report Form

General Information

EudraVigilance Local Report Number	EU-EC-10008321943
Sender Type	Regulatory authority
Sender's Organisation	EEA Regulator
Type of Report	Spontaneous
Primary source country	European Economic Area
Reporter's qualification	Healthcare Professional
Case serious?	Yes

Patient

Age	Age Group	Sex
7 Years		Female

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness[1]
Haematoma	8.0 Days	Fatal	death.
Decompensation cardiac	8.0 Days	Fatal	death.
Acute exacerbation of chronic bronchitis	6.0 Days	Fatal	death.

Drug Information

Role[2]	Drug	Duration	Dose	Units in Interval	Action taken

Drug Information *(cont.)*

Info[3]	Drug	Indication	Pharm. Form	Route of Admin.

1 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 Drug role: **S**=suspect; **C**=concomitant; **I**=interacting; **N**=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