SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	DOMINICAN REPUBLIC		PRIVACY		Unk	Unk	Unk	16	MAY	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Other Serious Criteria: Congenital Anomaly, Medically Significant
At the time of the baby's birth, the esophagus was not connected [Esophageal atresia]
respiratory arrest [Neonatal respiratory arrest]
premature labor at 33 weeks/ baby's birth [Premature birth]

Case Description: This is a spontaneous report received from a Consumer or other non HCP.

A neonate patient born to a mother who, while pregnant, received rsv

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: 20-MAY-2025
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Abrysvo (RSV VACCINE PROT.SUBUNIT PREF 2V) Powder for solution for injection {Lot # LY1791; Exp.Dt.
#2) Abrysvo (RSV VACCINE PROT.SUBUNIT PREF 2V (DEVICE **(Continued on Additional Information Page)**

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) DOSE 1, SINGLE	#1) Other
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Maternal immunization (Maternal immunisation)
#2) Maternal immunization (Maternal immunisation)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 23-APR-2025 / 23-APR-2025	#1) 1 day
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown		

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Pfizer S.A.
Laura Arce Mora
Avenida Escazú, Torre Lexus, piso 7. Escazú
San Jose, COSTA RICA

26. REMARKS

24b. MFR CONTROL NO.
PV202500061104

24c. DATE RECEIVED BY MANUFACTURER
21-MAY-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
04-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

vaccine prot.subunit pref 2v (ABRYSVO), on 23Apr2025 as dose 1, single (Lot number: LY1791, Expiration Date: 31Jan2026) for maternal immunisation. The mother of the patient was 35 years old. The mother was 33 weeks pregnant at the event onset. The mother is expected to deliver one baby(s). The mother's relevant medical history and concomitant medications were not reported. The following information was reported: OESOPHAGEAL ATRESIA (death, congenital anomaly, medically significant) with onset 16May2025, outcome "fatal", described as "At the time of the baby's birth, the esophagus was not connected"; PREMATURE BABY (medically significant) with onset 16May2025, outcome "unknown", described as "premature labor at 33 weeks/ baby's birth"; NEONATAL RESPIRATORY ARREST (death, medically significant) with onset 20May2025, outcome "fatal", described as "respiratory arrest". Therapeutic measures were taken as a result of oesophageal atresia. The patient date of death was 20May2025. Reported cause of death: "At the time of the baby's birth, the esophagus was not connected", "respiratory arrest". It was not reported if an autopsy was performed.
Clinical course: The mother went into premature labor at 33 weeks on 16May2025. At the time of the baby's birth, the esophagus was not connected, and surgery was performed three days after birth. The surgery went well, but the following day the baby suffered respiratory arrest. The baby passed away on 20May2025 (five days after birth).

Amendment: This follow-up report is being submitted to amend previously reported information: Add event "premature baby" and narrative updated.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Abrysvo (RSV VACCINE PROT.SUBUNIT PREF 2V) Powder for solution for injection {Lot # LY1791; Exp.Dt. 31-JAN-2026}; Regimen #1	DOSE 1, SINGLE; Other	Maternal immunization (Maternal immunisation)	23-APR-2025 / 23-APR-2025; 1 day
#2) Abrysvo (RSV VACCINE PROT.SUBUNIT PREF 2V (DEVICE CONSTITUENT)) Powder for solution for injection; Regimen #1	; Unknown	Maternal immunization (Maternal immunisation)	Unknown; Unknown