SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	DOMINICAN REPUBLIC		PRIVACY		35 Years	Female	Unk		Unk		

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: Medically Significant
preterm labor at 33 weeks [Premature delivery]

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

A 35-year-old female patient (pregnant) received rsv vaccine prot.subunit pref 2v (ABRYSVO), on 23Apr2025 as dose 1, single (Lot number: LY1791, Expiration Date: 31Jan2026) at the age of 35 years for maternal immunisation. The patient was 33 weeks pregnant at the event onset.

(Continued on Additional Information Page)

- ☐ PATIENT DIED
- ☐ 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) Unknown
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Maternal immunisation (Maternal immunisation)
#2) Maternal immunisation (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		Date of LMP for pregnancy

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.
PV202500061103

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

The patient is expected to deliver one baby(s). The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PREMATURE DELIVERY (medically significant), outcome "unknown", described as "preterm labor at 33 weeks". The baby was delivered premature, delivery date 16May2025. Clinical detail: The patient used Abrysvo by the direction of her physician on 23Apr2025. The patient 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: "from License Party" "RSV vaccine prot.subunit pref 2v is under agreement with LUIS E. BETANCES & CO, C. POR A" were removed from narrative.

Follow-up (30May2025): This is a spontaneous follow-up report received from the same contactable reporter.
Updated information: Age at vaccination.

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; Unknown	Maternal immunisation (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 immunisation (Maternal immunisation)	Unknown; Unknown