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	COSTA RICA		PRIVACY		39 Years	Female	70.00 kg	29	MAR	2025	

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

Nausea [Nausea]
Profuse vomiting [Vomiting]
Watery diarrhea [Watery diarrhea]
headache [Headache]
General malaise [General malaise]
Sore throat [Sore throat]
Tiredness [Tiredness]
Cough [Cough]
nasal congestion [Nasal congestion]
Rhinorrhea [Rhinorrhea]

(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 # LR6137; 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) Intramuscular
#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) 28-MAR-2025 / 28-MAR-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
20-AUG-2024		Date of LMP for pregnancy
Unknown	Relevant Med History started in adolescence, under control	Asthma (Asthma)
Unknown	Relevant Med History started in adolescence	Rhinitis NOS (Rhinitis)

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
Downgraded Report

24b. MFR CONTROL NO.
202500069277

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

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

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

DATE OF THIS REPORT
24-APR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Bronchial inflammation [Bronchitis]
Shortness of breath [Shortness of breath]

Case Description: This is a spontaneous report received from a Pharmacist from a sales representative.

A 39-year-old female patient (pregnant) received rsv vaccine prot.subunit pref 2v (ABRYSVO), on 28Mar2025 as dose 1, single (Lot number: LR6137, Expiration Date: Jul2026) intramuscular for maternal immunisation. The patient's relevant medical history included: "Asthma" (unspecified if ongoing), notes: started in adolescence, under control; "Rhinitic" (unspecified if ongoing), notes: started in adolescence; "Previous pregnancy" (unspecified if ongoing); "one living child" (unspecified if ongoing). Date of last menstrual period: 20Aug2024. The patient was 31 weeks pregnant at the time of exposure to rsv vaccine prot.subunit pref 2v. The patient was 31 weeks pregnant at the event onset. The patient is expected to deliver one baby(s) on 20May2025. There were no concomitant medications.
The following information was reported: MALAISE (non-serious) with onset 29Mar2025 at 04:00, outcome "recovered with sequelae", described as "General malaise"; NAUSEA (non-serious) with onset 29Mar2025 at 04:00, outcome "recovered"; VOMITING (non-serious) with onset 29Mar2025 at 04:00, outcome "recovered", described as "Profuse vomiting"; DIARRHOEA (non-serious) with onset 29Mar2025 at 04:00, outcome "recovering", described as "Watery diarrhea"; HEADACHE (non-serious) with onset 29Mar2025 at 04:00, outcome "recovered with sequelae"; BRONCHITIS (non-serious) with onset 2025, outcome "recovered with sequelae", described as "Bronchial inflammation"; COUGH (non-serious) with onset 2025, outcome "recovering"; RHINORRHOEA (non-serious) with onset 2025, outcome "recovered", described as "Rhinorrhea"; DYSPNOEA (non-serious) with onset 2025, outcome "recovering", described as "Shortness of breath"; OROPHARYNGEAL PAIN (non-serious) with onset 2025, outcome "recovered", described as "Sore throat"; FATIGUE (non-serious) with onset 2025, outcome "recovered with sequelae", described as "Tiredness"; NASAL CONGESTION (non-serious) with onset 2025, outcome "recovered". Relevant laboratory tests and procedures are available in the appropriate section. Therapeutic measures were not taken as a result of nausea, vomiting, diarrhoea, headache, malaise, oropharyngeal pain, fatigue, cough. Therapeutic measures were taken as a result of nasal congestion, rhinorrhoea, bronchitis, dyspnoea.

Additional information: The patient was not allergic to any vaccine, medication, food, or other previous products. Neither the father nor the mother smoked, drank alcohol nor consume illicit drugs during this pregnancy. The mother has not had any problems before the delivery. The birth has not yet occurred. It was reported that shortness of breath did not resolve with antihistamines or salbutamol. The patients took salbutamol for bronchitis, cetirizine for rhinorrhea and saline nasal wash for nasal congestion

Follow-up (09Apr2025): This is a spontaneous follow-up report received from the same pharmacist.
Updated information: patient data (added: height and weight), pregnancy information added, medical history data (added: Asthma, Rhinitis, Previous pregnancy and one living child), lab data added, suspect product data (added: route of administration and expiration date), event data (added new events: Sore throat, Tiredness, cough, Nasal congestion, Rhinorrhea, Bronchitis and Shortness of breath), outcome data (updated: Watery diarrhea and Headache to recovering/resolving, Vomiting, Nausea to recovered/resolved and General malaise to not recovered/not resolved) and additional information.

Follow-up (21Apr2025): This is a spontaneous follow-up report received from the same pharmacist.
Updated information: outcome updated for events malaise, headache, tiredness and bronchitis (recovered/resolved with sequel), outcome updated for events cough, dyspnea (recovering), outcome updated for event rhinorrhea, nasal congestion, sore throat (recovered/resolved). Treatment received for bronchitis, rhinorrhea and nasal congestion. Treatment not received for fatigue, oropharyngeal pain, cough and additional information

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	30-AUG-2024	Prenatal care	unknown results	
2	10-OCT-2024	Prenatal care	unknown results	
3	14-NOV-2024	Prenatal care	unknown results	
4	19-DEC-2024	Prenatal care	unknown results	
5	17-JAN-2025	Prenatal care	unknown results	
6	10-FEB-2025	Prenatal care	unknown results	
7	17-FEB-2025	Prenatal care	unknown results	

Mfr. Control Number: 202500069277

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
8	08-APR-2025	Prenatal care	unknown results	
9		Serology test Negative	Negative	

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 # LR6137; Exp.Dt. JUL-2026}; Regimen #1	DOSE 1, SINGLE; Intramuscular	maternal immunization (Maternal immunisation)	28-MAR-2025 / 28-MAR-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

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown	Relevant Med History	Gravida I (Primigravida);
Unknown	Relevant Med History	Parity 1 (Primiparous);