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		32 Years	Female	Unk	27	AUG	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: Medically Significant
lower back pain along with pelvic pain (contractions) [Contractions uterine increased]
lower back pain along with pelvic pain (contractions) [Low back pain]
lower back pain along with pelvic pain (contractions) [Pelvic pain female]
fever [Fever]
muscle pain [Muscle pain]
burning sensation when urinating [Urethral burning on micturition]
chills [Chills]
sore throat [Sore throat]

(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
#2) Abrysvo (RSV VACCINE PROT.SUBUNIT PREF 2V (DEVICE CONSTITUENT)) Powder for solution for injection

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 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) 27-AUG-2025 / 27-AUG-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
22-DEC-2024		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.
202500172233

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

24c. DATE RECEIVED BY MANUFACTURER
28-AUG-2025

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

DATE OF THIS REPORT
03-SEP-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

headache [Headache]

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

A 32-year-old female patient (pregnant) received rsv vaccine prot.subunit pref 2v (ABRYSVO), on 27Aug2025 as dose 1, single (Batch/Lot number: unknown) at the age of 32 years, in left arm for maternal immunisation. Date of last menstrual period: 22Dec2024. The patient was 35 weeks pregnant at the time of exposure to rsv vaccine prot.subunit pref 2v. The patient was 35 weeks pregnant at the event onset. The patient is expected to deliver a baby(s) on 28Sep2025. The patient's relevant medical history and concomitant medications were not reported. The patient did not receive any other vaccines on the same date as the vaccine(s) for which was reporting. The patient did not receive any other vaccines within 4 weeks prior to the vaccine(s) for which was reporting. The patient did not taking any other medications within 2 weeks of the event starting.
The following information was reported: DYSURIA (non-serious) with onset 27Aug2025 at 18:00, outcome "recovering", described as "burning sensation when urinating"; CHILLS (non-serious) with onset 27Aug2025 at 18:00, outcome "recovering"; PYREXIA (non-serious) with onset 27Aug2025 at 18:00, outcome "recovering", described as "fever"; HEADACHE (non-serious) with onset 27Aug2025 at 18:00, outcome "recovering"; UTERINE HYPERTONUS (medically significant), BACK PAIN (non-serious), PELVIC PAIN (non-serious) all with onset 27Aug2025 at 18:00, outcome "recovering" and all described as "lower back pain along with pelvic pain (contractions)"; MYALGIA (non-serious) with onset 27Aug2025 at 18:00, outcome "recovering", described as "muscle pain"; OROPHARYNGEAL PAIN (non-serious) with onset 27Aug2025 at 18:00, outcome "recovering", described as "sore throat". The events "lower back pain along with pelvic pain (contractions)", "fever", "muscle pain", "burning sensation when urinating", "chills", "sore throat" and "headache" required physician office visit. Clinical course: On the same day the patient received the vaccine, at 6 p.m. the patient began experiencing severe symptoms including lower back pain along with pelvic pain (contractions), fever, muscle pain, burning sensation when urinating, chills, sore throat, and headache. These symptoms increased in frequency as the hours passed, with the peak of pain occurring at 2 a.m. The patient went to the private medical center to be examined by her OB-GYN and to assess possible adverse effects. The patient was prescribed acetaminophen and rest. Therapeutic measures were taken as a result of uterine hypertonus, back pain, pelvic pain, pyrexia, myalgia, dysuria, chills, oropharyngeal pain, headache.