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		
		Day	Month	Year				Day	Month	Year
PRIVACY	PANAMA		PRIVACY		36 Years	Female	Unk	26	FEB	2025

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

had to inject herself this time, maybe she did it wrong, she felt like the treatment didn't go in as deeply as it should have [Wrong technique in device usage process]
allergic reaction/itch [Allergic reaction]
caused swelling and it stayed in one area [Injection site swelling]

Case Description: This is a spontaneous report received from a Consumer or other non HCP, Program ID: 164974.

A 36-year-old female patient received etanercept (ENBREL), (Batch/Lot

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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) Enbrel (ETANERCEPT) Solution for injection in pre-filled syringe
#2) Enbrel (ETANERCEPT (DEVICE CONSTITUENT)) Solution for injection in pre-filled syringe

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 50 mg, once a week	#1) Unknown
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Unknown
#2) Unknown

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#1) Unknown
#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.
PV202500025673

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

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

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

DATE OF THIS REPORT
10-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

number: unknown) at 50 mg weekly (50 mg, once a week). The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: HYPERSENSITIVITY (non-serious) with onset 26Feb2025, outcome "unknown", described as "allergic reaction/itch"; INJECTION SITE SWELLING (non-serious) with onset 26Feb2025, outcome "unknown", described as "caused swelling and it stayed in one area"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious) with onset 26Feb2025, outcome "unknown", described as "had to inject herself this time, maybe she did it wrong, she felt like the treatment didn't go in as deeply as it should have". The action taken for etanercept was unknown.

Additional information: The patient reported that sine she started the treatment, she had never had an allergic reaction until last Wednesday (26Feb2025). She did not know if she injected it incorrectly and that's why she had the reaction. She wanted advice on what she could use to calm the itching it caused. The treatment has worked very well for her, but since she had to inject herself this time, she felt like the treatment didn't go in as deeply as it should have, which caused swelling and it stayed in one area.

The information on the batch/lot number for etanercept will be requested and submitted if and when received.
Follow-up (10Apr2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.