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	PANAMA		PRIVACY		51 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)

redness (erythema) in the area of the injection [Injection site redness]
allergic reaction on the body [Allergic reaction]
it was applied intradermally [Incorrect route of product administration]

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

A 51-year-old female patient received etanercept (ENBREL), (Lot number: LL4200, Expiration Date: May2027) at 50 mg weekly, intradermal.

(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) Enbrel (ETANERCEPT) Solution for injection in pre-filled syringe {Lot # LL4200; Exp.Dt. MAY-2027}
#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, weekly	#1) Intradermal
#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.
PV202500088178

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

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

DATE OF THIS REPORT
18-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: INJECTION SITE ERYTHEMA (non-serious), outcome "recovered", described as "redness (erythema) in the area of the injection"; HYPERSENSITIVITY (non-serious), outcome "unknown", described as "allergic reaction on the body"; INCORRECT ROUTE OF PRODUCT ADMINISTRATION (non-serious), outcome "unknown", described as "it was applied intradermally". The action taken for etanercept was unknown. Therapeutic measures were taken as a result of hypersensitivity.

Additional Information: The nurse indicated that the patient applied her weekly dose, but did not do it by the subcutaneously, it was applied intradermally, which caused a reaction: redness (erythema) in the area of the injection, however, she clarified that the discomfort was temporary. On 12Aug2025, the patient reported an allergic reaction on the body after receiving the medication. The patient mentioned taking an antihistamine before the administration of the medication but continued to show symptoms of an allergic reaction lasting three days.

Follow-up (12Aug2025): This is a spontaneous follow-up report received from a Consumer or other non HCP.
Updated information: reporter data (added: consumer), suspect data (added: route of administration), event data (added: Allergic reaction) and additional information.