SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		45 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)

it had given her results but not as the doctor expected [Drug effect incomplete]

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

A 45-year-old female patient received etanercept (ENBREL), (Batch/Lot number: unknown) for ankylosing spondylitis. The patient's relevant medical history included: "spondylitis" (unspecified if ongoing), notes: More than 20 years of having spondylitis.

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

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK	#1) Unknown
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) ankylosing spondylitis (Ankylosing spondylitis)
#2) ankylosing spondylitis (Ankylosing spondylitis)

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	Relevant Med History	Spondylitis (Spondylitis)
	More than 20 years of having spondylitis	

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.
PV202500082840

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

24c. DATE RECEIVED BY MANUFACTURER
09-JUL-2025

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

DATE OF THIS REPORT
11-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's concomitant medications were not reported.
The following information was reported: THERAPEUTIC PRODUCT EFFECT INCOMPLETE (non-serious), outcome "unknown", described as "it had given her results but not as the doctor expected". The action taken for etanercept was unknown.

Additional Information: The patient had ankylosing spondylitis (more than 20 years of having it) and had already been on the treatment for more than a year and a half, it had given her results but not as the doctor expected. She suffered from chronic pain, but what they told her was that the disease was already so advanced that there was already damage and that those damages were what caused her pain. She always had the pain but now she was going for more studies because even with the orthopedist she was because of the wear and tear it caused, the pain persisted and now they sent her to another specialty. What she wanted to consult was that for the next appointment the doctor was going to evaluate the studies, the tests that had to be done, but it was very likely that she would suspend the treatment for a while to see how her body reacted. If she pushed back what little she had been able to achieve (walk a little more, stand a little more, do more things with better mobility). Only that when she started to exercise a little more the pain worsened, that's why the doctor said that it could be that it was not having the effect she needed, so she wanted to have a guide that if that was normal, that perhaps the medication was not valid, that this disease was already very advanced. Within two months she had an appointment with another specialist.

No follow-up attempts are possible. Batch/lot number is not provided, and it cannot be obtained.