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		64 Years	Female	Unk			2025

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

had been experiencing a flare-up of her Ankylosing Spondylitis for nearly a month [Clinical flare reaction]
in the most recent box, three pens were also defective/was completely unable to trigger two of them [Device mechanical jam]
in the most recent box, three pens were also defective/was completely unable to trigger two of them [Device defective]
in the most recent box, three pens were also defective/was completely unable to trigger two of them [Mechanical device firing issue]
in the most recent box, three pens were also defective/was completely unable to trigger two of them [Drug dose omission by device]

(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 {Lot # HJ4933; Exp.Dt. JUN-2026}
#2) Enbrel (ETANERCEPT (DEVICE CONSTITUENT)) Solution for injection in pre-filled pen {Lot # HJ4933}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 50 mg, weekly	#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 to Ongoing	Relevant Med History	Ankylosing spondylitis (Ankylosing 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.
202500150060

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

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

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

DATE OF THIS REPORT
30-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: This is a spontaneous report received from a Consumer or other non HCP from product quality group and medical information team.

A 64-year-old female patient received etanercept (ENBREL), (Lot number: HJ4933, Expiration Date: Jun2026) at 50 mg weekly, Device Lot Number: HJ4933, Device Expiration Date: Jun2026. The patient's relevant medical history included: "Ankylosing Spondylitis" (ongoing). The patient's concomitant medications were not reported.
The following information was reported: CONDITION AGGRAVATED (non-serious) with onset 2025, outcome "not recovered", described as "had been experiencing a flare-up of her Ankylosing Spondylitis for nearly a month"; DEVICE MECHANICAL ISSUE (non-serious), DEVICE DEFECTIVE (non-serious), DEVICE MALFUNCTION (non-serious), DRUG DOSE OMISSION BY DEVICE (non-serious) all with onset Jul2025, outcome "unknown" and all described as "in the most recent box, three pens were also defective/was completely unable to trigger two of them". The action taken for etanercept was unknown.

Additional information: Patient had been using Enbrel 50 mg (etanercept), for several years and had never had any issues with its application. However, with the previous treatment box from Jun2025 and the current one from Jul2025, both dispensed at the hospital pharmacy, the patient encountered problems with several pens. From the Jun2025 box, three out of four pens were defective. It was very difficult to administer the medication because the cap would not trigger properly. After much effort, the patient managed to use them. Unfortunately, in the most recent box, three pens were also defective. The patient was completely unable to trigger two of them, and the third one only worked with great difficulty. As a result, the patient had been experiencing a flare-up of her Ankylosing Spondylitis for nearly a month.

Causality for "had been experiencing a flare-up of her ankylosing spondylitis for nearly a month" and "in the most recent box, three pens were also defective/was completely unable to trigger two of them" was determined associated to device constituent of etanercept (malfunction).