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	COSTA RICA		PRIVACY		56 Years	Female	Unk		Unk	

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

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
had developed a condition that left her with vision in only one eye [Blindness, one eye]

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

A 56-year-old female patient received etanercept (ENBREL), (Batch/Lot number: unknown) at 50 mg weekly for arthritis. The patient's relevant medical history and concomitant medications were not reported.

(Continued on Additional Information Page)

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, weekly	#1) Unknown
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) arthritis (Arthritis)
#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.
PV202500098759

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

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

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

DATE OF THIS REPORT
19-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The following information was reported: BLINDNESS UNILATERAL (medically significant), outcome "unknown", described as "had developed a condition that left her with vision in only one eye". The action taken for etanercept was unknown. Clinical course: The patient not enrolled in the program indicated that she had been using the medication Enbrel for approximately nine years. She mentioned that, since the pandemic, she had developed a condition that left her with vision in only one eye. She was provided with the enrollment process so she could access the benefits. The patient stated that she suffers from arthritis and had been seen by several doctors. A meeting was held with multiple doctors because the one who had been treating them passed away.

The information on the batch/lot number for etanercept will be requested and submitted if and when received.

Amendment (DSU): This follow-up report is being submitted to amend previously reported information: patient information updated.