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	DOMINICAN REPUBLIC		PRIVACY		46 Years	Female	Unk		Unk	

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

scleroderma/she had been prescribed ENBREL [Off label use in unapproved indication]

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

A 46-year-old female patient received etanercept (ENBREL), since 02Jul2025 (Batch/Lot number: unknown) at 50 mg weekly for scleroderma. The patient's relevant medical history and concomitant medications were not reported. Past drug history included: Enbrel, notes: Unknown formulation.

(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
#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) scleroderma (Scleroderma)
#2) scleroderma (Scleroderma)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 02-JUL-2025 / 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	Past Drug Event Unknown formulation	Enbrel (ENBREL)

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.
PV202500080452

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
07-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: PV202500080452

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The following information was reported: OFF LABEL USE (non-serious), described as "scleroderma/she had been prescribed ENBREL". Relevant laboratory tests and procedures are available in the appropriate section.

Additional information: The patient stated that she had scleroderma and mentioned that she had been prescribed Enbrel 50 mg. She also reported that the doctor had given her a list of tests to undergo.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Investigation	unknown results	