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	PANAMA		PRIVACY		49 Years	Male	Unk	19	APR	2025

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

pain in the right arm [Painful R arm]
he had not been on the therapy for a month because he was unable to pick up the medication due to work [Therapy interrupted]

Case Description: This non-serious solicited report (PANSL2025082128) was reported to Amgen on 22/APR/2025 by a consumer from a commercial program (PSP10981) and involves a 49 year old male patient who experienced pain in the right arm [PT: pain in extremity], he had not been on the therapy for a month because he was unable to pick up the medication due to work [PT: therapy interrupted] while receiving Amgevita, Single Dose

(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
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) AMGEVITA (adalimumab) Solution for injection
#2) single dose prefilled syringe (single dose prefilled syringe) Device

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 40 milligram (every 15 days)	#1) Subcutaneous use
#2)	#2) Unknown

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 02-AUG-2022 / Ongoing	#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	Current Condition	Rheumatoid arthritis (Rheumatoid arthritis)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Amgen Ltd.
Ana Carolina Uribe
Cra 7 No. 123-35 Torre 123 Piso 6
Bogotá, COLOMBIA
Phone: 57 3157008539

26. REMARKS

24b. MFR CONTROL NO.
PANSL2025082128

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

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

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

DATE OF THIS REPORT
30-APR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Prefilled Syringe (adalimumab, manufacturer Amgen).

No historical medical condition was reported. The patient's current medical condition included rheumatoid arthritis. No concomitant medications were provided. No co-suspect medications were reported.

The patient began Amgevita, Single Dose Prefilled Syringe on 02/AUG/2022. On 19/APR/2025, the patient had pain in his right arm and that he had not been on the therapy for a month because he was unable to pick up the medication due to work. No treatment information was received. The outcome of the event pain in extremity was reported as not recovered/not resolved. The outcome of the event therapy interrupted was reported as unknown.

The other manufacturer reported that the event pain in extremity was possibly related to Amgevita. The causal relationship between the events pain in extremity and Amgevita Single Dose Prefilled Syringe was not provided by the consumer. The causal relationship between the event therapy interrupted and Amgevita, Single Dose Prefilled Syringe was not provided by the consumer. No follow-up attempts are possible. No further information is expected.