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		Unk	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)

Ineffective drug [Drug ineffective]
Cessation of therapy [Therapy cessation]
positive anti-drug antibodies [Antibody test abnormal]

Case Description: This non-serious spontaneous report (DOMSP2025057067) was reported to Amgen on 19/MAR/2025 by a physician and involves a female patient who had ineffective drug [PT: drug ineffective], cessation of therapy [PT: therapy cessation], positive anti-drug antibodies [PT: antibody test abnormal] while receiving Amgevita (adalimumab, manufacturer Amgen).

(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

15. DAILY DOSE(S)
#1) UNK

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown

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

18. THERAPY DATES(from/to)
#1) Unknown

19. THERAPY DURATION
#1) Unknown

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

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

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.
DOMSP2025057067

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

24c. DATE RECEIVED BY MANUFACTURER
19-MAR-2025

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

DATE OF THIS REPORT
26-MAR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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 on an unknown date. As per treating physician, despite adherence to treatment, the patient decided not to continue the drug due to lack of effectiveness (ineffective drug / Cessation of therapy). The length of time the patient was on treatment was unknown, however treating physician indicates that this patient had positive anti-drug antibodies, so she was led to switch treatment. No treatment information was received. The outcome of the events drug ineffective, therapy cessation, antibody test abnormal were reported as unknown. Action taken with Amgevita was withdrawn for the events drug ineffective and antibody test abnormal.

The physician reported that the event drug ineffective was possibly related to Amgevita. The causal relationship between the events therapy cessation, antibody test abnormal and Amgevita was not provided by the physician. The reporter does not and will never have access to lot number. No follow-up attempts are possible. No further information is expected.