CIOMS FORM

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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	PANAMA		PRIVACY		18 Years	Male	Unk	16	APR	2021	☐ PATIENT DIED

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

Amgevita treatment did work, but not as well as the doctor expected [Drug effect less than expected] causality analysis of therapeutic failure was inappropriate use [Off label use]

Case Description: This non-serious solicited report (PANSL2025081135) was reported to Amgen on 21/APR/2025 by a consumer from a commercial program (PSP10850) and involves a 18-year-old male patient who had Amgevita treatment did work, but not as well as the doctor expected [PT: drug effect less than expected] while receiving Amgevita (adalimumab,

(Continued on Additional Information Page)

☐ 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

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

15. DAILY DOSE(S)
#1) 40 milligram

16. ROUTE(S) OF ADMINISTRATION
#1) Subcutaneous use

17. INDICATION(S) FOR USE
#1) Crohn's Disease (Crohn's disease)

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

18. THERAPY DATES(from/to)
#1) 16-APR-2021 / Unknown

19. THERAPY DURATION
#1) 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	Crohn's disease (Crohn's disease)

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.
PANSL2025081135

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

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

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

DATE OF THIS REPORT
29-APR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

manufacturer Amgen). Off label use was reported.

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

The patient began Amgevita on 16/APR/2021. The patient began treatment with the injectable Amgevita 40 milligrams from 16/APR/2021 for the indication of Crohn's Disease. The patient has not been using Amgevita for more than two years because his treating physician switched him to another treatment. The Amgevita dose he was taking was not adequate, and then the dose was increased, but it still did not work. For this reason, he switched to another medication with private insurance. The Amgevita treatment did work, but not as well as the doctor expected. The last dose of Amgevita he received was in late 2022 and early 2023. He understands that he would not resume treatment with Amgevita. The causality analysis of therapeutic failure was inappropriate use (Off label use). No treatment information was received. The outcome of the event drug effect less than expected was reported as unknown. Action taken with Amgevita was withdrawn for the event drug effect less than expected.

The causal relationship between the event drug effect less than expected and Amgevita was not pro-vided by the consumer. No follow-up attempts are possible. No further information is expected.