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		
		Day	Month	Year				Day	Month	Year
PRIVACY	PANAMA		PRIVACY		85 Years	Male	Unk	19	JUN	2025

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

patient died of stomach bleeding [Gastric haemorrhage]

Case Description: This serious solicited report (PANSL2025140349) was reported to Amgen on 14/JUL/2025 by a consumer from a commercial program (PSP10850) and involves a 85-year-old male patient who had died of stomach bleeding [PT: gastrointestinal haemorrhage], while receiving Amgevita (adalimumab, manufacturer Amgen).

No historical medical condition was reported. The patient's current medical condition included Crohn's disease.

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED Date: 19-JUN-2025
- ☐ 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

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 40 milligra (Continued on Additional Information Page)

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) 28-JAN-2025 / 19-JUN-2025

19. THERAPY DURATION
#1) 4 months 23 days

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.
PANSL2025140349

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

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

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

DATE OF THIS REPORT
21-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

No concomitant medications were provided. No co-suspect medications were reported.

The patient began Amgevita on 28/JAN/2025. It was reported that the daughter reported that on 19/JUN/2025, her father died of stomach bleeding. She stated that she would not provide further information about what happened. The cause of death was stomach bleeding. It was unknown if an autopsy was performed. No treatment information was received. The outcome of the event gastrointestinal haemorrhage was reported as fatal.

The consumer reported that the event gastrointestinal haemorrhage was possibly related to Amgevita. No follow-up attempts are possible. No further information is expected.

Company Comment: This safety report does not necessarily reflect a conclusion by Amgen that adalimumab, caused or contributed to the adverse event reported. However, consistent with regulatory reporting requirements, this case is being reported because it contains one or more suspected adverse reactions.

This individual case report does not change the safety profile of the product.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) AMGEVITA (adalimumab) Solution for injection; Regimen #1	40 milligram (AMGEVITA, 40 MG en 0.8 ML, every 15 Days); Subcutaneous use	Crohn's disease (Crohn's disease)	28-JAN-2025 / 19-JUN-2025; 4 months 23 days