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		36 Years	Female	Unk	11	MAY	2023

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

Other Serious Criteria: Medically Significant, Medically Important
herniated disc/required surgery to schedule as treatment [Herniated disc]
Headache [Headache]
Severe pain in her hips [Pain in hip]

Case Description: This non-serious Solicited report (PANSL2023084108) was reported to Amgen on 15/MAY/2023 by a consumer from a patient support program (PSP10850) and involves a 36 year old female patient who had severe pain in her hips [PT: arthralgia] 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: Medically Important

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) AMGEVITA (adalimumab) Solution for injection

15. DAILY DOSE(S)
#1) 40 milligram, q2wk

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

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

18. THERAPY DATES(from/to)
#1) 15-APR-2023 / Ongoing

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.
PANSL2023084108

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

24c. DATE RECEIVED BY MANUFACTURER
20-JUN-2025

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

DATE OF THIS REPORT
28-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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. The physician advised patient to initiate prednisolone and Enantyum. No co-suspect medications were reported.

The patient began Amgevita on 15/APR/2023. Approximately 3 weeks later, on 11/MAY/2023, the patient had severe pain in her hips. No treatment information was received. The outcome of the event arthralgia was reported as not recovered/not resolved. Action taken with Amgevita was continued for the event arthralgia.

The causal relationship between the event arthralgia and Amgevita was not provided by the consumer. The follow up not been requested.

ADDITIONAL INFORMATION RECEIVED ON 09/JUN/2025:
On 31/MAY/2025, the patient experienced headache approximately two days after administering the medication (Amgevita) [PT: headache]. She managed it by taking acetaminophen. Treatment for the event headache included Acetaminophen (acetaminophen). The outcome of event headache was reported as recovered resolved. The event headache was resolved on 02/JUN/2025. Action taken with Amgevita was continued for the event headache. The consumer reported that the event headache was possibly related to Amgevita. No follow-up attempts are possible. No further information is expected.

ADDITIONAL INFORMATION RECEIVED ON 20/JUN/2025:
This case upgraded to serious. It was reported that the patient had herniated disc [PT: intervertebral disc protrusion] and intensity was mild. The outcome of the event intervertebral disc protrusion was reported as not recovered/not resolved. Action taken with Amgevita was continued for the event intervertebral disc protrusion. The consumer reported that the event intervertebral disc protrusion was not related to Amgevita.

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