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		34 Years	Female	Unk		OCT	2024

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

she found out she was pregnant, she was approximately one month pregnant [Maternal exposure during pregnancy]

Case Description: This non-serious solicited report (PANSL2025082923) was reported to Amgen on 24/APR/2025 by a consumer from a commercial program (PSP10981) and involves a 35 year old female patient who found out she was pregnant, she was approximately one month pregnant [PT: maternal exposure during pregnancy] 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

(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) Rheumatoid arthritis (Rheumatoid arthritis)

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

18. THERAPY DATES(from/to)
#1) 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		Date of LMP for pregnancy
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.
PANSL2025082923

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

24c. DATE RECEIVED BY MANUFACTURER
24-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

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's obstetric history and last menstrual period was not provided.

The patient began Amgevita on an unknown date (start of therapy unknown until NOV/2024). It was reported that, the patient believed the last dose of Amgevita she took was in OCT/2024. She was not currently using Amgevita treatment because her rheumatologist discontinued it in NOV/2024 due to her pregnancy. When she found out she was pregnant, she was approximately one month pregnant and was still using Amgevita, she was still taking her current dose. Resuming Amgevita treatment depends on the physician prescription. There were no adverse events reported at this time. No treatment information was received. The outcome of the event maternal exposure during pregnancy was reported as unknown. Action taken with Amgevita was temporarily withheld for the event maternal exposure during pregnancy.

The causal relationship between the event maternal exposure during pregnancy and Amgevita was not provided by the consumer. The reporter does not and will never have access to lot number. Follow up has been requested.

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, q2wk (1 ampoule every 15 days); Subcutaneous use	Rheumatoid arthritis (Rheumatoid arthritis)	Unknown; Unknown