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	COSTA RICA		PRIVACY		59 Years	Female	Unk	04	AUG	2025

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

received the intradermal injection at a pharmacy [Subcutaneous injection formulation administered by other route]

Case Description: This non-serious Spontaneous report with a product complaint (CRISP2025157435) was reported to Amgen on 05/AUG/2025 by a other health professional and involves a 59 year old female patient who received the intradermal injection at a pharmacy [PT: incorrect route of product administration] while receiving Prolia, Single Dose Prefilled Syringe.

(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) Prolia (denosumab) Solution for injection
#2) single dose prefilled syringe (single dose prefilled syringe) Device

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 60 milligram, q6mo/6.00 Months	#1) Intradermal use
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Osteoporosis (Osteoporosis)
#2) Osteoporosis (Osteoporosis)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 04-AUG-2025 / Ongoing	#1) Unknown
#2) Unknown	#2) 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	Osteoporosis (Osteoporosis)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Amgen Biotecnológica S.A.S.
Ana Carolina Uribe
Cra 7 No. 123-35 Torre 123 Piso 6
Bogotá, COLOMBIA
Phone: 57 3157008539

26. REMARKS

24b. MFR CONTROL NO.
CRISP2025157435

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

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

DATE OF THIS REPORT
26-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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

The patient began Prolia, Single Dose Prefilled Syringe on 04/AUG/2025. On 04/AUG/2025, the patient received the intradermal injection at a pharmacy. No treatment information was received. The outcome of the event incorrect route of product administration was reported as unknown.

The consumer reported that the event incorrect route of product administration was possibly related to Prolia. The causal relationship between the event incorrect route of product administration and Prolia Single Dose Prefilled Syringe was not provided by the other health professional. Follow up has been requested.

ADDITIONAL INFORMATION RECEIVED ON 21/AUG/2025:
In this version the patient had confirmed that she purchased the product from a pharmacy and was offered immediate administration, but instead of subcutaneous administration, it was administered intradermally. The error occurred at the stage of administration. Inadequate training of pharmacy staff was the factor contributed to the error. Trained pharmacy staff could have prevented this error from occurring. The dose was not repeated, and the second dose will be administered in six months was the action taken because of the error. The pharmacist administered the product. This was her first dose.