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	GUATEMALA		PRIVACY		10 Years	Male	Unk		Unk	

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

broke a vial/broke a cartridge [Device breakage]

Case Description: This is a spontaneous report received from a Consumer or other non HCP from product quality group, Program ID: 164974.

A 10-year-old male patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 1.4 mg 1x/day (1.4 mg, 1x/day (at night)).

(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

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Genotropin Pen (SOMATROPIN) Solution for injection
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.4 mg, 1x/day (at night)	#1) Unknown
#2)	#2) Unknown

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

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#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		

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Pfizer S.A.
Laura Arce Mora
Avenida Escazú, Torre Lexus, piso 7. Escazú
San jose, COSTA RICA

26. REMARKS

24b. MFR CONTROL NO.
PV202500077352

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

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

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

DATE OF THIS REPORT
17-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE BREAKAGE (non-serious), outcome "unknown", described as "broke a vial/broke a cartridge".
Additional information: The patient's caregiver had a question about a GENOTROPIN cartridge. Her son was using GENOTROPIN, and his husband bought a GENOTROPIN C cartridge from a place that sells it in redacted. Her question was whether the cartridge had to be the same as the GENOTROPIN sold here in redacted, because his husband broke a vial and got one to replace it, but from another place, but from a supplement store that sells products for gyms. She also mentioned that the rubber on the GENOTROPIN C was on the outside, unlike the Pfizer Genotropin, which had the rubber on the inside. Lot Drug lot number is F95581, Expiry date is Nov2027; Pen lot number is JW1066, Pen expiration date is Jan2026 (pending clarification). On 07Jul2025, the nurse stated that when he/she got to the office, the person in charge had questions about a medication, but this medication was not purchased here in redacted. The distributor did not give or sell it or redacted Social Security. This medication was then purchased in redacted, called GENOTROPIN C, and was purchased outside of Pfizer's authorized distributors. GENOTROPIN C cartridges were evaluated, noting that the cartridges were seen as counterfeit and it was suggested to the patient's manager not to be used because they were counterfeit, as is normally a factory-made cartridge manufactured by Pfizer. Note that the nurse never viewed Pfizer products at the consultancy, only GENOTROPIN C. Sample of the product is not available to be returned.

The reporter considered "broke a vial/broke a cartridge" not related to somatropin. Causality for "broke a vial" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 11Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: No further investigation was needed for this complaint.

The information on the batch/lot number for somatropin will be requested and submitted if and when received.