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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	DOMINICAN REPUBLIC		PRIVACY		9 Years	Female	Unk		Unk		

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

had a problem changing the cartridge and it did not come out. I put it on, but it did not work [Device mechanical jam]
part of the medication was wasted (leaked) [Device leakage]

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

A 9-year-old female patient (unknown if pregnant) received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 1.2 mg 1x/day (1.2 mg, 1x/day (at night)).

(Continued on Additional Information Page)

- ☐ 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) 1.2 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.
PV202500059166

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

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

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

DATE OF THIS REPORT
04-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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 MECHANICAL ISSUE (non-serious), outcome "unknown", described as "had a problem changing the cartridge and it did not come out. I put it on, but it did not work"; DEVICE LEAKAGE (non-serious), outcome "unknown", described as "part of the medication was wasted (leaked) ". The action taken for somatropin was unknown.

Causality for "had a problem changing the cartridge and it did not come out. i put it on, but it did not work" and "part of the medication was wasted (leaked) " was determined associated to device constituent of somatropin (malfunction).

Additional information: Patient manager indicated: "I had a problem when I was going to change the ampoule, and it did not come out. I put it in, but it did not work, part of the medicine was wasted and I'm afraid to put it back in because I don't want to waste the medicine."

Product Quality Group provided investigational results on 02Jun2025 for somatropin (device constituent): Investigation Summary and Conclusion: 02Jun2025. Site Investigation: No further investigation was required as no valid lot number or returned sample was available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. Two distinct Complaint Issues of "Difficulty Loading/Unloading Cartridge and Leaking During Loading" were reported. However, these two distinct Complaint Issues maps to the same Hazard and Hazardous Situation. The Risk Management File was reviewed to confirm that the Hazard(s) and Hazardous Situation(s) associated with the Complaint Issue are documented in the Hazard Analysis (INX100281795, Version # 9.0). All complaint investigations are trended. There is no current trend alert documented. Investigation Summary Complete Date(GMT): 02Jun2025.

Batch/lot number is not provided, and it cannot be obtained.

Follow-up (02Jun2025): This is a follow-up report from product quality group providing investigation results

Updated information: clinical course updated.
Follow-up (04Jul2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.