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		12 Years	Male	Unk	13	MAY	2025	

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

cartridge contents dropped more than usual from 12 to 6 [Device fluid leak]
cartridge dropped more than usual from 12 to 6 / mother is worried that she does not know for sure if she gave her all that amount [Inaccurate delivery by device]
mother is worried that she does not know for sure if she gave her all that amount [Incorrect dose administered by device]

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

(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 {Lot # LR7825; Exp.Dt. MAY-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # LR7825}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 2.0 mg, daily at night	#1) Unknown
#2) 2.0 mg/noche	#2) Unknown

17. INDICATION(S) FOR USE
#1) Growth hormone deficiency (Growth hormone deficiency)
#2) Growth hormone deficiency (Growth hormone deficiency)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) JUL-2024 / Unknown	#1) Unknown
#2) JUL-2024 / 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	Relevant Med History	Hypothyroidism (Hypothyroidism)

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.
202500101162

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

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

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

DATE OF THIS REPORT
10-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 12-year-old male patient received somatropin (GENOTROPIN PEN), since Jul2024 (Lot number: LR7825, Expiration Date: May2027) at 2 mg daily (2.0 mg, daily at night) for growth hormone deficiency, Device Lot Number: L207, Device Expiration Date: 31Oct2026. The patient's relevant medical history included: "Hypothyroidism" (unspecified if ongoing). The patient's concomitant medications were not reported.
The following information was reported: DEVICE LEAKAGE (non-serious) with onset 13May2025 at 21:30, described as "cartridge contents dropped more than usual from 12 to 6"; DEVICE DELIVERY SYSTEM ISSUE (non-serious) with onset 13May2025 at 21:30, described as "cartridge dropped more than usual from 12 to 6 / mother is worried that she does not know for sure if she gave her all that amount"; INCORRECT DOSE ADMINISTERED BY DEVICE (non-serious) with onset 13May2025 at 21:30, described as "mother is worried that she does not know for sure if she gave her all that amount". The action taken for somatropin was unknown.

Causality for "cartridge contents dropped more than usual from 12 to 6", "cartridge dropped more than usual from 12 to 6 / mother is worried that she does not know for sure if she gave her all that amount" and "mother is worried that she does not know for sure if she gave her all that amount" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 07Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: The complaint for 'marked the 2mg dose and that when administering the drug, she was able to notice that the contents of the cartridge fell more' of 'Genotropin Pen Injectable' was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of a reference sample, an analysis of the complaint history for the involved scope and Annual Product Review. A complaint sample was not returned.The complaint is not confirmed. No root cause or CAPA were identified as the complaint was not confirmed. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability and patient safety. The Issue Escalation (NTM) process determined that no regulatory notification was required.The final scope was determined to be the associated lot of the reported lot L207. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue, Excess Dose, was reported. 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.

Follow-up (14May2025): This is a spontaneous follow-up report received from the product quality group.
Updated information: " Device fluid leak" was added as an event. This case has been upgraded to malfunction reportable.

Follow-up (26Jun2025): Follow-up attempts are completed.

Follow-up (07Jul2025): This is a spontaneous follow-up report received from product quality group. Updated information included: investigation results.