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		11 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)

the needle keeps leaking liquid [Device leakage]

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

An 11-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: LD7549, Expiration Date: Mar2027) at 1 mg daily, Device Lot Number: D154, Device Expiration Date: 31Mar2027.

(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 # LD7549; Exp.Dt. MAR-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D154}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1 mg, daily	#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.
PV202500072402

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

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

DATE OF THIS REPORT
12-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

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 LEAKAGE (non-serious), outcome "unknown", described as "the needle keeps leaking liquid".

Causality for "the needle keeps leaking liquid" was determined associated to device constituent of somatropin (malfunction).

Additional Information: Patient's caregiver stated: "I'm calling because my son's Genotropin device, when I insert the Genotropin and then remove the needle, the needle keeps leaking liquid, I think the device has something that is not working properly. And I would not want to take the risk of continuing to use such an expensive medication only for it to go to waste". As of 24Jun2024, the person in charge of the patient said: "This week they sent me a nurse because the device, when I gave my son the injection, I waited about 10 to 15 seconds for all the liquid to come out, and when I removed it, the device kept leaking liquid, little drops of liquid, which it did not do it before. The nurse told me to change the needle, I changed it, but the needle kept leaking".

Product Quality Group provided investigational results on 07Aug2025 for somatropin (device constituent): Investigation Summary and Conclusion: 07Aug2025. Site investigation: Container Leaking During Prep/Use. The complaint for "the needle keeps leaking liquid" of Genotropin Pen Injectable was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of 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 D154. 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, Leaking During Loading, 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. Investigation Summary Complete Date(GMT): 07Aug2025. COMPLAINT-816941 Is The Original Record Of Follow Up COMPLAINT-818641.

Follow-up (02Aug2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Follow-up (07Aug2025): This is a follow-up report from product quality group providing investigation results

Updated information: Lot# and Expiry date of Drug and Device updated.