SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		8 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)

lost more than half of the medication [Device leakage]
made the decision not to administer the medication to the patient for the time being [Drug dose omission by device]
when I had to load the new dose, I had that inconvenience and it no longer allows me to dose in the device [Health care provider instructions for product use lacking]

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

(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 {Lot # LR7825; Exp.Dt. MAY-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution **(Continued on Additional Information Page)**

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.6 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.
PV202500056642

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

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

DATE OF THIS REPORT
14-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

An 8-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: LR7825, Expiration Date: May2027) at 1.6 mg daily and second regimen (Batch/Lot number: unknown) at 0.6 mg daily, Device Lot Number: D126, Device Expiration Date: 31Jan2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE LEAKAGE (non-serious), described as "lost more than half of the medication"; DRUG DOSE OMISSION BY DEVICE (non-serious), described as "made the decision not to administer the medication to the patient for the time being"; PRODUCT COMMUNICATION ISSUE (non-serious), described as "when I had to load the new dose, I had that inconvenience and it no longer allows me to dose in the device". The action taken for somatropin was unknown.

Causality for "lost more than half of the medication", "made the decision not to administer the medication to the patient for the time being" and "when i had to load the new dose, i had that inconvenience and it no longer allows me to dose in the device" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 03Jul2025 and 09Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site Investigation (Pfizer Manufacturing Site): Battery Died Before Expiry/Display Not Functioning. The complaint for "it no longer allows me to mark the units" 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(s) of the reported lot D126. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution. Site Investigation (Pfizer Manufacturing Site): Container Leaking During Prep/Use. The complaint for "medication came out" of Genotropin Pen Injectable was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of reference samples, 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 lots of the reported lot D126. 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. Two distinct Complaint Issues of "Unable/Difficult to Set/Draw Dose" and "Leaking During Loading" were reported. However, these two distinct Complaint issues map to the same Hazard/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 not a current trend alert documented.

Additional Information: The patient manager indicated: "My GENOTROPIN device, saw that it no longer allows me to mark there the units that I need to administer to my daughter and saw that yesterday (07May2025) that I was going to change it, I lost more than half of the medication because when I wanted to see, it shot up by itself and the medication came out. So, I want to see if someone can support me or how I can acquire a new device, I make the space, I interrupt my activities there in order to solve that, because yes, as I say, yesterday when I had to load the new dose, I had that inconvenience and it no longer allows me to dose in the device the dose that I have to administer to my daughter." On 09May2025, the nurse indicated: "There was a quality complaint from the person in charge, when he made the replacement of the cartridge of GENOTROPIN 12mg, when they wanted to put the ideal dose which is 0.6mg, they could only put 0.2mg, and the cartridge spilled completely, leaving a minimal part in the cartridge." The person in charge made the decision not to administer the medication to the patient for the time being, until it was verified that it works properly. Took into account that the counseling with the patient's caregiver was virtual, however, the nurse recommended that face-to-face counseling should be coordinated to verify the pen. At the time of making the satisfaction survey call, the patient's mother did not report any report and did not refer that she needs other advice. Upon a follow-up received on 20Jun2025, the nurse stated that during this virtual consultation held on 08May at 4:00 PM with patient, the caregiver reported that while performing the cartridge replacement, she attempted to set the dose to 0.6 mg (the patient's prescribed dose). However, after the replacement, she was only able to load 0.2 mg, and an entire cartridge spilled, leaving only a minimal amount remaining. The caregiver stated that she followed the procedure correctly, noting that she had already performed three cartridge replacements previously. In the nurse opinion, an in-person inspection of the device was necessary to ensure it was in proper working condition

Follow-up (20Jun2025): Follow-up attempts are completed.

Follow-up (20Jun2025): This is a spontaneous follow-up report received from a Consumer or other non HCP and a Nurse.
Updated information: product details (dosage regimen) and clinical course.

Follow-up (03Jul2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Expiration date of product and QC results added.

Follow-up (09Jul2025): This is a follow-up report from product quality group providing investigation results.
Updated information included: Investigation conclusion added.

Mfr. Control Number: PV202500056642

ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Genotropin Pen (SOMATROPIN) Solution for injection; Regimen #2	0.6 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D126}; Regimen #1	; Unknown	Unknown	Unknown; Unknown