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		7 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)

Sometimes a little drop of medicine appears up there. Also, when I'm done, a little drop remains/device is leaking [Device leakage]
after putting the dose and administering it is counted 10 seconds after making the injection click and continues to drip slowly. [Poor quality device used]

Case Description: This is a spontaneous report received from Consumer or other non HCPs 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 # R7825; 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) 0.4 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.
PV202500041777

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

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

DATE OF THIS REPORT
16-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 7-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: R7825, Expiration Date: May2027) at 0.4 mg daily, second regimen (Lot number: lr7825, Expiration Date: May2027) at 0.4 mg daily, third regimen (Lot number: ND7549, Expiration Date: May2027) at 0.4 mg daily and fourth regimen (Lot number: LD7549, Expiration Date: Mar2027) at 0.4 mg daily, Device Lot Number: D154, Device Expiration Date: 31Mar2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE LEAKAGE (non-serious), described as "Sometimes a little drop of medicine appears up there. Also, when I'm done, a little drop remains/device is leaking"; POOR QUALITY DEVICE USED (non-serious), described as "after putting the dose and administering it is counted 10 seconds after making the injection click and continues to drip slowly.". The action taken for somatropin was unknown.

Causality for "sometimes a little drop of medicine appears up there. also, when i'm done, a little drop remains/device is leaking" and "after putting the dose and administering it is counted 10 seconds after making the injection click and continues to drip slowly." was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 16Apr2025 and 14Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site Investigation (Pfizer Manufacturing Site): Container Leaking During Prep/Use. The complaint for "the device begins to drip slowly." 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 "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. Two distinct Complaint Issues, Leaking During Loading and Leaking After Administration were reported. However, Leaking After Administration maps to the Hazard/Hazardous Situation of H10-10, Hazard "Functionality - Critical Performance / Delivery Quantity" Hazardous Situation "Single subtherapeutic dose administered in pediatric/adult population" and Leaking During Loading maps to the Hazard/Hazardous Situation of H10-01, Hazard "Delivery Quantity"/Hazardous Situation "Dose not administered (single) or delay of dose administration in pediatric/adult population". 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).

Additional Information: The nurse reported "The patient's mother complained that the button wasn't working properly, but that wasn't true. I received it and everything worked fine. It was just a bit stiff when pressing the button, but that was normal". The patient's caregiver said: "I don't know if it's normal, but when I gave the injection, as I inserted the needle, a small drop of medication sometimes appeared right at the top. Also, when I finished, a drop remained. Am I doing something wrong?". It should be noted that the caregiver did not have access to the batch number or expiration date of the pen or the medication. Upon follow-up received on 15Apr2025, the patient's caregiver informed: "Yesterday, we had a virtual appointment with the nurse. When we mentioned the pen releasing a few drops, he told us that this was putting the medication. He said that if it continued happening even after following his instructions, we should contact them again for further guidance or to consider a replacement". Upon follow-up received on 12May2025, the patient's caregiver informed: "I had reported a pen because it always released a few drops before and after the injection." A verification appointment had previously been scheduled, and the nurse confirmed that a replacement was indeed necessary. Upon follow-up received on 15May2025, the nurse stated: "During the guidance session with the patient on 14May, the caregiver reported that the device was leaking. By evaluating the device, it was possible to define the placebo and indeed, by placing the needle in the device with the placebo without any dose, the device begins to drip slowly. It is also observed that after dosing and administration of the medication, the corresponding ten seconds are counted, including counting up to the corresponding ten seconds after the injection time, it continues to drip after administration of the medication, slow dripping, but it is observed that it has leaks, so it suggests that a device change be made in this case". Upon follow-up received on 21May2025, the patient's caregiver informed: "I had requested a pen replacement. The nurse came and reported it, but I haven't received it yet. How long does that usually take?" He also mentioned: "According to the nurse, the pen was in good condition, but it still released a few drops before and after use". As of 20Jun2025, a reporter indicated that The person in charge said that the device was leaking, the Pen Lot Number D154, Case Lot Number LD7549 with Expiration Date Mar2027 is evaluated. And it was tested with a placebo and indeed when you put the needle without putting any dose of the drug it starts to drip slowly and after putting the dose and administering it is counted 10 seconds after making the injection click and continues to drip slowly. The device is observed leaking.

Follow-up (20Jun2025): This is a Spontaneous follow-up report received from Nurse, Program ID: 164974
Updated information: new dosage regimen added, and additional information updated

Amendment: This follow-up report is being submitted to amend previously reported information: event Poor quality device used added.

Follow-up (14Jul2025): This is a follow-up report from product quality group providing investigation results.
Updated information included: Investigation conclusion added.

Mfr. Control Number: PV202500041777

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 {Lot # lr7825; Exp.Dt. MAY-2027}; Regimen #2	0.4 mg, daily; Unknown	Unknown	Unknown; Unknown
#1) Genotropin Pen (SOMATROPIN) Solution for injection {Lot # ND7549; Exp.Dt. MAY-2027}; Regimen #3	0.4 mg, daily; Unknown	Unknown	Unknown; Unknown
#1) Genotropin Pen (SOMATROPIN) Solution for injection {Lot # LD7549; Exp.Dt. MAR-2027}; Regimen #4	0.4 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D154}; Regimen #1	; Unknown	Unknown	Unknown; Unknown