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		13 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)

need another training [Health care provider instructions for product use lacking]
when I was trying to get the air out, all the fluid went out [Device leakage]
she did it incorrectly, and the entire contents of the ampoule were wasted / made a misplacement of the medication and all the medication in the vial was wasted [Wrong technique in device usage process]

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

(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 # LR7824; Exp.Dt. JUN-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) 1.8 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.
PV202500076289

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

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

DATE OF THIS REPORT
22-AUG-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

164974.

A 13-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: LR7824, Expiration Date: Jun2027) at 1.8 mg daily and second regimen (Lot number: LD7551, Expiration Date: Jan2027) at 1.8 mg daily, Device Lot Number: D129, Device Expiration Date: 31Jan2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PRODUCT COMMUNICATION ISSUE (non-serious), outcome "unknown", described as "need another training"; DEVICE LEAKAGE (non-serious), outcome "unknown", described as "when I was trying to get the air out, all the fluid went out"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), outcome "unknown", described as "she did it incorrectly, and the entire contents of the ampoule were wasted / made a misplacement of the medication and all the medication in the vial was wasted". The action taken for somatropin was unknown.

Causality for "need another training", "when i was trying to get the air out, all the fluid went out" and "she did it incorrectly, and the entire contents of the ampoule were wasted / made a misplacement of the medication and all the medication in the vial was wasted" was determined associated to device constituent of somatropin (malfunction).

Additional information: Patient reported 'I want to report that last night, I was trying to prepare a blister and the blister when I was trying to get the air out, all the fluid went out. I need another training, please, because I have no way to medicate the child today, because my problem is when I'm taking the air out of the injection, the blister seems like I don't know, I don't know it. I put it on, she told me to kind of put it in 00 or in a row, and I did it incorrectly, and the entire contents of the ampoule were wasted, since I lost a dose, a complete blister.' As for 24Jun2025 Patient reported 'I reported the blister, but it turns out that I don't have a way to put it on today. When the nurse came, she made me one and I saw everything and I understood everything, but last night, when I ran out of dose, which I had to prepare another, all the liquid was thrown out and now I don't know how to prepare it and I don't want to leave the child unmedicated today, today I'm not going to put it because I'm afraid that another blister is going to break.' As for 26Jun2025 Nurse indicated: 'The mother tells me that when she went to place the medication, she made a misplacement of the medication and all the medication in the vial was wasted'.

Product Quality Group provided investigational results on 14Aug2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site investigation (Pfizer Manufacturing Site): Container Leaking During Prep/Use. The complaint for "trying to remove the air, all the liquid came out" of "Genotropin Pen" 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 "D129". 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 (INX# INX100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Product Quality Group provided investigational results on 19Aug2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: The following complaint was received for GENOTROPIN PEN: "the patient reported 'I want to report that last night, I was trying to prepare a blister and the blister when I was trying to get the air out, all the fluid went out. I need another training, please, because I have no way to medicate the child today, because my problem is when I'm taking the air out of the injection, the blister seems like I don't know, I don't know it. I put it on, she told me to kind of put it in 00 or in a row, and I did it incorrectly, and the entire contents of the ampoule were wasted, since I lost a dose, a complete blister.' As for 24Jun2025 Patient reported 'I reported the blister, but it turns out that I don't have a way to put it on today. When the nurse came, she made me one and I saw everything and I understood everything, but last night, when I ran out of dose, which I had to prepare another, all the liquid was thrown out and now I don't know how to prepare it and I don't want to leave the child unmedicated today, today I'm not going to put it because I'm afraid that another blister is going to break.' As for 26Jun2025 Nurse indicated: 'The mother tells me that when she went to place the medication, she made a misplacement of the medication and all the medication in the vial was wasted." The complaint was investigated by the manufacturing site.

Follow-up (08Aug2025): Follow-up attempts are completed.

Follow-up (14Aug2025): This is a follow-up report from product quality group providing investigation results.
Updated information included: Investigation conclusion added, lot number for device added

Follow-up (19Aug2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Product communication issue recoded to Health care provider instructions for product use lacking, Batch and lot tested and found within specifications ticked, investigation results added

Mfr. Control Number: PV202500076289

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 # LD7551; Exp.Dt. JAN-2027}; Regimen #2	1.8 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D129}; Regimen #1	; Unknown	Unknown	Unknown; Unknown