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	COSTA RICA		PRIVACY		16 Years	Male	Unk	28	JAN	2025

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

It was spilling [Device leakage]
The medication was changed/It was spilling, and it was full of bubbles [Device failure to prime]
It was full of bubbles/The medication was full of bubbles [Device physical property issue]
There was failure in adherence at the third day [Drug dose omission 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)

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
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.2 mg, daily	#1) Subcutaneous
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Short stature (Short stature)
#2) Short stature (Short stature)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 17-MAY-2024 / 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.
PV202500012991

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

24c. DATE RECEIVED BY MANUFACTURER
27-JUN-2025

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

DATE OF THIS REPORT
27-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 16-year-old male patient received somatropin (GENOTROPIN PEN), since 17May2024 (Batch/Lot number: unknown) at 1.2 mg daily, subcutaneous for short stature. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE PHYSICAL PROPERTY ISSUE (non-serious) with onset 28Jan2025, described as "It was full of bubbles/The medication was full of bubbles"; DEVICE LEAKAGE (non-serious) with onset 28Jan2025, described as "It was spilling"; DEVICE FAILURE (non-serious) with onset 28Jan2025, described as "The medication was changed/It was spilling, and it was full of bubbles"; DRUG DOSE OMISSION BY DEVICE (non-serious) with onset 28Jan2025, described as "There was failure in adherence at the third day". The action taken for somatropin was unknown.

Causality for "It was spilling", "The medication was changed/It was spilling, and it was full of bubbles", "It was full of bubbles/The medication was full of bubbles" and "There was failure in adherence at the third day" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 21Feb2025 for somatropin (device constituent): No further investigation is required as no valid lot number or returned sample is available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. Two distinct Complaint Issues of "Leaking During Prep/Use" and "Cannot Remove Air" 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's mother reported that two days ago (27Jan2025), the cartridge of the medication was changed, and it was used without problems or inconveniences. However, on 28Jan2025, yesterday, at night (day 3), the patient told her that the medication was strange. When it was checked, it was spilling, and it was full of bubbles. The total of the medication was 12 mg. They had applied 2.4 mg (total accumulated dose of the two days that she used the medication), therefore, 9.6 mg of medication should have remained in the cartridge. Nevertheless, the patient's mother reported that there was only approximately 5 mg left in the cartridge, and the medication was full of bubbles. She estimated that it was even less medication. She indicated that she was very afraid of using the drug in those conditions, consequently, she was going to be sent a nurse from the Pfizer program to check the device and the medication. She indicated that she could not afford another vial so soon, so there was failure in adherence at the third day, and there would be failure in adherence the next few days while the mother would manage to acquire the money to pay for the medication. As of 25Mar2025, the patient's mother inquired how she could request a new cartridge for the drug. She had asked for a new dose, but she was still missing the applicator. She had already received a response from Pfizer, and the pharmacy had already contacted her.

Follow-up (21Feb2025): This is a follow-up report from product quality group providing investigation results.

Follow-up (25Mar2025): This is a spontaneous follow-up report received from a Consumer or other non-HCP. Updated information: The onset date of the events was included. New event of ''Device physical property issue''. Clinical course updated.
Follow-up (27Jun2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.