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		14 Years	Male	Unk	17	JUL	2025

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

When trying to replace the cartridge, the medication spilled through various parts of the device [Device leakage]
red ball of the pen did not return to its place and the device could not be closed properly [Device mechanical jam]
has gone several days without receiving his dose [Drug dose omission by device]

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 # LT8412; Exp.Dt. AUG-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) 2.6 mg, 1x/day	#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) MAY-2025 / 17-JUL-2025	#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.
PV202500088169

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

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

DATE OF THIS REPORT
30-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

A 14-year-old male patient received somatropin (GENOTROPIN PEN), from May2025 (Lot number: LT8412, Expiration Date: Aug2027) to 17Jul2025 at 2.6 mg 1x/day, 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) with onset 17Jul2025, described as "When trying to replace the cartridge, the medication spilled through various parts of the device"; DRUG DOSE OMISSION BY DEVICE (non-serious) with onset 17Jul2025, described as "has gone several days without receiving his dose"; DEVICE MECHANICAL ISSUE (non-serious) with onset 17Jul2025, described as "red ball of the pen did not return to its place and the device could not be closed properly". The action taken for somatropin was temporarily withdrawn on 17Jul2025.

Additional information: The patient's mother reported issues with the administration of the growth hormone, which was recently started after switching brands. She stated that the patient correctly used the first cartridge following the instructional video but then interrupted the treatment for 15 days due to a trip without access to refrigeration, which was authorized by the physician. Upon attempting to resume treatment, the device malfunctioned. She reported that the red ball of the pen did not return to its place and the device could not be closed properly. When trying to replace the cartridge, the medication spilled through various parts of the device. The red ball did not reappear, and the pen still does not fit into its case. She is concerned because the patient son has gone several days without receiving his dose. The nurse reported that two months ago (May2025) the patient was switched to the Pfizer brand medication. Since then, there have been issues when changing the cartridge, as on both occasions the medication has spilled. She mentions that the device (pen) is malfunctioning. The required dose is 2.6 mg, but the pen does not allow more than 0.8 mg to be set; it gets stuck and does not allow purging (removing air from the syringe). Once the cartridge is inserted, the button to administer the medication does not go down. The patient's caregiver reported that she previously requested a nurse visit because the device (pen) or the medication was not working properly. The nurse has already visited and confirmed that the pen is cross-threaded, which is preventing it from dispensing the medication. She states that since Wednesday, the patient has not been able to receive the dose and urgently requests support to obtain a new pen as soon as possible. Upon a follow-up received on 21Jul2025, the patient's mother stated that the nurse had confirmed the Genotropin pen was cross-threaded, and since the previous Thursday (17Jul2025), she had been unable to administer the medication to her son. She had consulted with the pharmacy, and they informed her that they did not know when the devices would arrive at the warehouse. Therefore, she was unaware of when she would receive her device.

Causality for "when trying to replace the cartridge, the medication spilled through various parts of the device", "red ball of the pen did not return to its place and the device could not be closed properly" and "has gone several days without receiving his dose" was determined associated to device constituent of somatropin (malfunction).

Follow-up (21Jul2025 and 23Jul2025): This is a spontaneous follow-up report from a Consumer or other non HCP and from product quality group, Program ID: 164974.
Updated information: product details (stop date and action taken updated to temporarily withdrawn), device details (lot expiration date), event details (onset date) and clinical course.