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	COSTA RICA		PRIVACY		14 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)

has gone several days without receiving his dose [Drug dose omission by device]
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]

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

(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 # 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 / 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.
PV202500088169

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

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

DATE OF THIS REPORT
24-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), since May2025 (Lot number: LT8412, Expiration Date: Aug2027) at 2.6 mg 1x/day, Device Lot Number: D154. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DRUG DOSE OMISSION BY DEVICE (non-serious), described as "has gone several days without receiving his dose"; DEVICE LEAKAGE (non-serious), described as "When trying to replace the cartridge, the medication spilled through various parts of the device"; DEVICE MECHANICAL ISSUE (non-serious), 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 unknown.

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

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.