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	GUATEMALA		PRIVACY		11 Years	Female	Unk		Unk		

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

the button to apply the Genotropin device is hard [Device mechanical jam]
cartridges were not in perfect condition (they had abnormalities) and did not fit properly into the device [Device physical property issue]

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.

An 11-year-old female patient received somatropin (GENOTROPIN PEN), (Lot number: LJ9497, Expiration Date: Jan2027) at 1.4 mg 1x/day, Device

(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 # LJ9497; Exp.Dt. JAN-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D123}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.4 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) 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.
PV202500085583

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

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

DATE OF THIS REPORT
20-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

Lot Number: D123, Device Expiration Date: 31Jan2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE MECHANICAL ISSUE (non-serious), outcome "unknown", described as "the button to apply the Genotropin device is hard"; DEVICE PHYSICAL PROPERTY ISSUE (non-serious), outcome "unknown", described as "cartridges were not in perfect condition (they had abnormalities) and did not fit properly into the device".

Additional Information: Patient caregiver informs you that they want the nurse visit as soon as possible since the button to apply the Genotropin device is hard. Later, the patient asked for another consultation to check the pen again, and it was confirmed that the issue was not with the pen, but with the cartridges, as they were purchased in Panama and brought to Guatemala. The problem with the pen was that the cartridges were not in perfect condition (they had abnormalities) and did not fit properly into the device. Due that, the pen was malfunctioning. The nurse advised the family not to use the medication anymore. Upon a follow-up received on 15Aug2025, an initial consultations with the patient on 23Jul2025 at 10am, a consultation had already been carried out for the revision of Pen and when reviewing it was in perfect condition for use. The afore mentioned advice is coordinated for the revision of the Pen Lot Number D126, Case with Lot Number KC8721 both with Expiration Date Jan2027, the Pen was evaluated again and it was observed in perfect condition again. When evaluating the Genotropin 12mg drug cartridge, the patient caregiver stated that this cartridge with Lot Number LJ9497 with Expiration Date Jan2027 was purchased in the Country of Panama and when evaluating them, they are observed with abnormalities and alterations. Therefore, the caregiver was instructed NOT to use this cartridge. And it was recommended to buy from the authorized Genotropin 12mg distribution center in Guatemala. This is all the information from this consultancy.

Product Quality Group provided investigational results on 24Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site investigation (Pfizer Manufacturing Site): No further investigation was required as no valid lot number or returned sample was available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened. Device engineering investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue, Injection Knob/Dial Issue, 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#100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Causality for "the button to apply the genotropin device is hard" and "cartridges were not in perfect condition (they had abnormalities) and did not fit properly into the device" was determined associated to device constituent of somatropin (malfunction).

The information on the batch/lot number for somatropin will be requested and submitted if and when received.

Follow-up (15Aug2025): This is a spontaneous follow-up report from a Nurse.
Updated information: suspect drug details, device details (lot number added), new event added ('Device physical property issue') and clinical course.