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	GUATEMALA		PRIVACY		6 Years	Female	Unk		Unk	

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

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

When they try to adjust it to set the eight millimeters, it doesn't work [Device mechanical 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.

A 6-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 0.8 mg daily (0.8 mg, daily (every night)), second regimen (Lot number: LN4285, Expiration Date:

(Continued on Additional Information Page)

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 **(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) 0.8 mg, daily (every night)	#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.
PV202500061096

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
16-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Feb2027) at 0.6 mg daily and third regimen (Lot number: HM4951, Expiration Date: 30Nov2026), Device Lot Number: L209, Device Expiration Date: 30Nov2026. 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 "When they try to adjust it to set the eight millimeters, it doesn't work". The action taken for somatropin was unknown.

Causality for "when they try to adjust it to set the eight millimeters, it doesn't work" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 14Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site Investigation (Pfizer Manufacturing Site): Injection Device Blocked/Cannot Set Dose/Deliver Dose/Injection Knob/Plunger Does Not/Never Moved. The complaint for "try to adjust it to set the eight millimeters, it doesn't work." of Genotropin Pen Injectable 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(s) of the reported lot L209. 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. Two distinct Complaint Issues of "Unable/Difficult to Set/Draw Dose and Difficulty Loading/Unloading Cartridge" were reported. However, these two distinct Complaint Issues maps to the same Hazard and 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 no current trend alert documented.

Additional Information: The patient's caregiver states the pen no longer worked, so they would like to know what applies in this case. When they try to adjust it to set the eight millimeters, it doesn't work. Nurse states: "Upon arriving at the visit, the patient's caregiver reported that during a cartridge replacement, it got stuck. That's why they requested in-person assistance. The pen was evaluated and tested it with a placebo and confirmed that the pen is in perfect working condition. The cartridge was reinserted, the one that had gotten stuck, and left everything ready for them to continue the treatment. The pen is in perfect condition". Upon a follow-up received on 20Jun2025, nurse stated that during this in-person consultation with patient on 20May at 4:00 pm, the person in charge reported that, at the time of replacing the cartridge, the pen no longer injected. Pen Lot Number: L209. Case Lot Number: HM4951. Expiration Date: Nov2026. Upon reviewing the pen using a placebo, it was confirmed that the device was in perfect working condition. Cartridge Lot Number LN4285, Expiration Date Feb2027, was left ready for use so that the patient could continue with the treatment. This was all the information available regarding this case.

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

Follow-up (20Jun2025): This is a spontaneous follow-up report received from a Consumer or other non HCP and a Nurse.
Updated information: product details (device lot number) and clinical course.

Follow-up (14Jul2025): This is a follow-up report from product quality group providing investigation results.
Updated information included: Investigation conclusion added.

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 # LN4285; Exp.Dt. FEB-2027}; Regimen #2	0.6 mg, daily; Unknown	Unknown	Unknown; Unknown
#1) Genotropin Pen (SOMATROPIN) Solution for injection {Lot # HM4951; Exp.Dt. 30-NOV-2026}; Regimen #3	UNK; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # L209}; Regimen #1	; Unknown	Unknown	Unknown; Unknown

Mfr. Control Number: PV202500061096

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