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		7 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)

I could not give her the injection last night [Drug dose omission by device]
locked and could not be unscrewed [Device mechanical jam]

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 7-year-old female patient received somatropin (GENOTROPIN PEN), first regimen since 09Oct2024 (Lot number: HL8272, Expiration Date: Jul2026) at 0.8 mg daily and second regimen (Lot number: HM4951, Expiration

(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 # HL8272; Exp.Dt. JUL-2026}
#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	#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) 09-OCT-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.
PV202500048789

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

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

DATE OF THIS REPORT
17-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Date: 30Nov2026) at 0.8 mg daily, 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: DRUG DOSE OMISSION BY DEVICE (non-serious), described as "I could not give her the injection last night"; DEVICE MECHANICAL ISSUE (non-serious), described as "locked and could not be unscrewed". The action taken for somatropin was unknown.

Causality for "i could not give her the injection last night" and "locked and could not be unscrewed" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 12Jun2025 for somatropin (device constituent): Investigation Summary and Conclusion: 12Jun2025. Site investigation: The complaint for "When I wanted to change the cartridge, the device was locked and not unlocked" 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. Site investigation: The complaint for "she wasn't doing it correctly and was doing this step horizontally when it has to be turned up, so she was having to lose the drug" 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 reported lot and 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 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. This complaint for "I could not give her the injection last night...locked and could not be unscrewed" & additional information from eQMS "today I tried again and I was already able to unscrew (plunger) the device without problems therefore I could change the cartridge" for Genotropin Pen is a reportable malfunction for the US. If it were to recur, it could likely cause or contribute to death or serious injury. This event is NOT a reportable malfunction for ROW since it could NOT lead to a serious deterioration in health. This event is 30-day US reportable and NOT reportable ROW. Product used for treatment. COMPLAINT-804789 Is related to COMPLAINT-805830. COMPLAINT-804789 Is related to COMPLAINT-809967. COMPLAINT-804789 Is related to COMPLAINT-809968.

Follow-up (24Apr2025): This is a spontaneous follow-up report received from reporter(s) Nurse. Program ID: 164974. Updated information: New reporter, dosage regimen, clinical course.

Follow-up (31May2025): Follow-up attempts are completed.

Follow-up (12Jun2025): This is a follow-up report from product quality group providing investigation results

Updated information: Device expiry date 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 # HM4951; Exp.Dt. 30-NOV-2026}; Regimen #2	0.8 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # L209}; Regimen #1	; Unknown	Unknown	Unknown; Unknown