SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	GUATEMALA		PRIVACY		3 Years	Female	Unk	14	MAY	2025

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

it's been three days with no medication coming out.

(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 # LN4285; Exp.Dt. FEB-2027}
#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) 0.6 mg, daily (at 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.
PV202500058000

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

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

DATE OF THIS REPORT
14-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

[Drug dose omission by device]
the medication did not come out of the needle [Device blockage]
the medication did not come out of the needle [Failure of delivery by device]
that the plunger of the pen did not return to the top, that is why a certain part of the cartridge spilled, that is, She did not make the replacement correctly [Device handling error]

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 3-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: LN4285, Expiration Date: Feb2027) at 0.6 mg daily (0.6 mg, daily (at night)) and second regimen (Lot number: LD7549, Expiration Date: Mar2027) at 0.6 mg daily (0.6 mg, daily (at night)), 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 USE ERROR (non-serious) with onset 14May2025, described as "that the plunger of the pen did not return to the top, that is why a certain part of the cartridge spilled, that is, She did not make the replacement correctly"; DRUG DOSE OMISSION BY DEVICE (non-serious), described as "it's been three days with no medication coming out."; DEVICE OCCLUSION (non-serious), DEVICE DELIVERY SYSTEM ISSUE (non-serious) and all described as "the medication did not come out of the needle". The action taken for somatropin was unknown.

Causality for "it's been three days with no medication coming out.", "the medication did not come out of the needle" and "that the plunger of the pen did not return to the top, that is why a certain part of the cartridge spilled, that is, she did not make the replacement correctly" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational summary and conclusion on 09Jul2025 for somatropin (device constituent): Site Investigation (Puurs): Injection Device Blocked/Cannot Set Dose/Deliver Dose/Injection Knob/Plunger Does Not/Never Moved The complaint for "the medication no longer comes out of the needle" of Genotropin Pen Injectable was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of a 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 of the reported lot D154. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution. Site Investigation (Puurs): Container Leaking During Prep/Use The complaint for "she performed a cartridge replacement and some of the medication spilled during the process" of "Genotropin Pen Injectable" was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of reference samples, 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 lots of the reported lot "D154". 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. The Complaint Issue "Injection Failure/Blocked" 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 (INX100281795, Version 9.0). All complaint investigations are trended. There is no current trend alert documented.

Additional information: On 15May2025: Nurse indicates: "In face-to-face counseling with this patient who went at two in the afternoon of May 14, the person in charge reports that she made a cartridge change and a certain part of the cartridge spilled in the refill. But it is observed that the plunger of the pen did not return to the top, that is why a certain part of the cartridge spilled, that is, She did not make the replacement correctly. She forgot the step of returning the plunger of the pen until it reached the top counterclockwise, it is important considering that the person in charge had already made three previous replacements, so she is given advice again from the beginning and the revision of the pen is carried out with a placebo again, The placebo and PEN is in perfect condition for use. It is worth mentioning that the person in charge of poor communication from the Social Security here in Guatemala never communicated with the Pfizer Me Cuida call center for the scheduling of the advice, that is, she did it on her own, yesterday she already received advice and obviously she did tell me that she was doing the procedure wrong." As of 20Jun2025, a reporter indicated that The person in charge said that she made a cartridge replacement and a certain part of the cartridge spilled since in the replacement the pen plunger did not return to the top counterclockwise, Pen Lot Number D154 Case Lot Number LD7549. Expiration Date Mar2027. Taking into account that he had already made three cartridge replacements. So advice is given on how to make the replacement correctly, and when checking the Pen it is in perfect condition for use. It is worth mentioning that due to poor communication from the Social Security he had not received the corresponding advice for the use of Genotropin 12mg.

Follow-up (15May2025): This is a spontaneous follow-up report received from a Nurse, Program ID: 164974. Updated information includes: new dosage regimen, new event (Device use error) and clinical course details.

Follow-up (20Jun2025): This is a Spontaneous follow-up report received from Nurse, Program ID: 164974

Mfr. Control Number: PV202500058000

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Updated information: Additional information updated.
Follow-up (27Jun2025): Follow-up attempts are completed.

Follow-up(09Jul2025): This is a follow-up report from product quality group providing investigation results.
Updated information: device lot expiration date added, event added, Investigation results updated.

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 # LD7549; Exp.Dt. MAR-2027}; Regimen #2	0.6 mg, daily (at night); Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D154}; Regimen #1	; Unknown	Unknown	Unknown; Unknown