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		3 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 medication did not come out of the needle [Failure of delivery by device]
certain part of the cartridge spilled since in the replacement the pen plunger did not return to the top counterclockwise [Wrong technique in device usage process]
it's been three days with no medication coming out.

(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 # LN4285; Exp.Dt. FEB-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) 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
15-AUG-2025

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

DATE OF THIS REPORT
20-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 5

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]

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), (Lot number: LN4285, Expiration Date: Feb2027) 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 DELIVERY SYSTEM ISSUE (non-serious), described as "the medication did not come out of the needle"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), described as "certain part of the cartridge spilled since in the replacement the pen plunger did not return to the top counterclockwise"; DRUG DOSE OMISSION BY DEVICE (non-serious), described as "it's been three days with no medication coming out.". The action taken for somatropin was unknown.

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 PRIVACY never communicated with the PRIVACY 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.

Product Quality Group provided investigational summary and conclusion on 09Jul2025 and 10Jul2025 for somatropin (device constituent): Site Investigation (Pfizer Manufacturing Site): 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 (Pfizer Manufacturing Site): 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.

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

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
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.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Follow-up (10Jul2025): This is a follow-up report from product quality group providing investigation results.
Updated information included: Investigation conclusion added.

Follow-up (15Aug2025): This is a spontaneous follow-up report received from a Nurse.
Updated information: product details (dosage regimen removed), device details, new event added ('Wrong technique in device usage process') and events details (events previously captured as 'Device blockage' and 'Device handling error' were removed).