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		2 Years	Male	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 vial does not go down [Device delivery system issue]
she considered that she was not placing the medication as it should [Wrong technique in device usage process]
have not placed the treatment correctly [Incorrect dose administered 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.

(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
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D126}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.4 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) 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.
PV202500017851

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

NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
23-MAY-2025

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

DATE OF THIS REPORT
23-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 5

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 2-year-old male patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 0.4 mg daily, Device Lot Number: D126, Device Expiration Date: 31Jan2027. 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 vial does not go down"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), described as "she considered that she was not placing the medication as it should"; INCORRECT DOSE ADMINISTERED BY DEVICE (non-serious), described as "have not placed the treatment correctly". The action taken for somatropin was unknown.

Causality for "the vial does not go down", "she considered that she was not placing the medication as it should" and "have not placed the treatment correctly" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational summary and conclusion on 17Mar2025 for somatropin (device constituent): Site investigation (Puurs): The complaint for "first dose the pen doesn't dispense it until she puts in the second dose" 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 of the reported lot D126. 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, Difficulty Loading/Unloading Cartridge, 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.

Product Quality Group provided investigational summary and conclusion on 14Apr2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: The complaint of for the responsible indicated that had been with the treatment for approximately 20 days but she had doubts because she had realized that the vial did not went down, she had realized that it was not working or that she had not placed the treatment correctly. In fact, she received the training but had been on the medication for 20 days, and in theory the ampoule should last for 30 days, but the ampoule was almost the same, so she considered that she was not placing the medication as it should, so she wanted to do the consultation to see if it was something that she was doing wrong because then if not, she was ''puncturing'' it for pleasure for GENOTROPIN PEN was investigated by the manufacturing site.

Additional Information: The responsible indicated that had been with the treatment for approximately 20 days but she had doubts because she had realized that the vial did not went down, she had realized that it was not working or that she had not placed the treatment correctly. In fact, she received the training but had been on the medication for 20 days, and in theory the ampoule should last for 30 days, but the ampoule was almost the same, so she considered that she was not placing the medication as it should, so she wanted to do the consultation to see if it was something that she was doing wrong because then if not, she was "puncturing" it for pleasure. As of 20Feb2025, they put the medication vial but when the dose was set it was not delivered.

Follow-up (20Feb2025, 17Feb2025 and 13Feb2025): This is a spontaneous follow-up report received from a Nurse, Program ID: 164974. Updated information includes lot number and expiration date, updated clinical course.

Follow-up(17Mar2025): This is a follow-up report from product quality group providing investigation results.
Updated information: device lot expiration date updated, Investigation results updated.

Follow-up (27Mar2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Amendment: This follow-up report is being submitted to amend previous information: to add narrative reported on 14Apr2025, submit the Health Impact Code and Medical Device Component Code and check the ''Batch and lot tested and found within specifications''.
Follow-up (23May2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.