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	DOMINICAN REPUBLIC		PRIVACY		14 Years	Male	Unk		NOV	2024	

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

The Pen was hard, she could not turn it back [Device mechanical jam]
The Pen was damaged, it was hard [Device physical property issue]
The patient had not taken the medication for about a month [Drug dose omission by device]

Case Description: The initial case was missing the following minimum criteria: No adverse event. Upon receipt of follow-up information on 19Dec2024, this case now contains all required information to be considered valid. 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 # W159}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.3 mg, 1x/day (every 24 hours)	#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.
PV202400166470

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

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

DATE OF THIS REPORT
08-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 6

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 14-year-old male patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 1.3 mg 1x/day (1.3 mg, 1x/day (every 24 hours)), Device Lot Number: W159, Device Expiration Date: 31May2024. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE MECHANICAL ISSUE (non-serious) with onset Nov2024, described as "The Pen was hard, she could not turn it back"; DRUG DOSE OMISSION BY DEVICE (non-serious) with onset Nov2024, described as "The patient had not taken the medication for about a month". The action taken for somatropin was unknown.

Causality for "the pen was hard, she could not turn it back" and "the patient had not taken the medication for about a month" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 02Jan2025 for somatropin (device constituent): Investigation Summary and Conclusion: No further investigation is required as no valid lot number or returned sample is available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened. COMPLAINT-776068 Is The Original Record Of Follow Up COMPLAINT-777004.

Product Quality Group provided investigational results on 14Feb2025 for somatropin (device constituent): Site Investigation (Pfizer Manufacturing Site): The complaint for "the pen doesn't work, it's "hard", it can't go back" 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 "W159". The reported defect is not representative of the quality of the batch. The complaint for "had been damaged" 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 W159. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution. MDCP Investigation Summary and Conclusion: The following complaint was received for It was reported that the nurse provided the Pen in 2022, and the Pen did not work, it was hard, and she could not turn it back. The patient's mother was going to stop the medication if the Pen was not replaced. Later, the patient's mother reported that the Pen was damaged, it was hard. Consequently, the patient had not taken the medication for about a month. for GENOTROPIN PEN, The complaint was investigated by the manufacturing site.

Product Quality Group provided investigational summary and conclusion on 21Feb2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: The complaint of nurse says, "The patient's mother told me that I gave her the pen in 2022, the pen doesn't work, it's "hard", it can't go back, and she will stop applying the medication if her pen isn't replaced" Product: Genotropin 5.3mg was investigated by the manufacturing site.

Product Quality Group provided investigational summary and conclusion on 05May2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: The following complaint was received for It was reported that the nurse provided the Pen in 2022, and the Pen did not work, it was hard, and she could not turn it back. The patient's mother was going to stop the medication if the Pen was not replaced. Later, the patient's mother reported that the Pen was damaged, it was hard. Consequently, the patient had not taken the medication for about a month." for GENOTROPIN PEN," The complaint was investigated by the manufacturing site.

Additional information: It was reported that the nurse provided the Pen in 2022, and the Pen did not work, it was hard, and she could not turn it back. The patient's mother was going to stop the medication if the Pen was not replaced. Later, the patient's mother reported that the Pen was damaged, it was hard. Consequently, the patient had not taken the medication for about a month. The patient's mother indicated that the 5.3 mg Pen was not "reaching" her locality, and the physician had to make an indication for the 12 mg.

Follow-up (02Jan2025): This is a follow-up report from the product quality group. Updated information included: investigation results.
Follow-up (08Feb2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.
Follow-up (14Feb2025): This is a follow-up report from the product quality group. Updated information included: investigation results.
Follow-up(21Feb2025): This is a follow-up report from the product quality group. Updated information included: investigation results.
Follow-up (28Feb2025): This is a follow-up report from the product quality group. Updated information included: investigation results.
Follow-up (05May2025): This is a follow-up report from the product quality group. Updated information included: investigation results.