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		6 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)

he is without medication [Drug dose omission by device]
2 years ago it expired and pen is not working /it did not want to change the corresponding dose, only lines appeared on the screen but it did not want to set the medication.

(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 **(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) 0.4 mg, daily	#1) Unknown
#2) 0.6 mg, daily	#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) MAR-2022 / Unknown	#1) Unknown
#2) MAR-2022 / 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.
PV202400082066

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

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

DATE OF THIS REPORT
03-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 8

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

[Device mechanical issue]

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 6-year-old male patient received somatropin (GENOTROPIN PEN), first regimen since Mar2022 (Batch/Lot number: unknown) at 0.4 mg daily and second regimen since Mar2022 (Batch/Lot number: unknown) at 0.6 mg daily, Device Lot Number: W131, Device Expiration Date: 31Dec2023. 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 "he is without medication"; DEVICE MECHANICAL ISSUE (non-serious), described as "2 years ago it expired and pen is not working /it did not want to change the corresponding dose, only lines appeared on the screen but it did not want to set the medication.". The action taken for somatropin was unknown.

Causality for "he is without medication" and "2 years ago it expired and pen is not working /it did not want to change the corresponding dose, only lines appeared on the screen but it did not want to set the medication." was determined associated to device constituent of somatropin (malfunction).

Additional information: On 24Jun2024 Nurse reported that the device the patient had had expired since 2023. Lote/Batch: SA3317 (inside) | W131 (outside).

Product Quality Group provided investigational results on 17Sep2024. Investigation Summary and Conclusion: The complaint for "only lines appear on the screen" 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 "W131". The reported defect is not representative of the quality of the batch.

Product Quality Group provided investigational results on 16May2025 for somatropin (device constituent): Investigation Summary and Conclusion: No further investigation was required as no valid lot number or returned sample was available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened.

Product Quality Group provided investigational results on 01Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: No further investigation was required as no valid lot number or returned sample was available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened.

Follow-up (24Jun2024): This is a spontaneous follow-up report received from Nurse, Program ID: (164974)
Updated information included: New reporter, event verbatim device malfunction updated, additional information updated.

Follow-up (24Jun2024): This is a spontaneous follow-up report received from Consumer or other non HCP from product quality group
Updated information included: Device lot number.
Follow-up (07Aug2024): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Follow-up (17Sep2024): This is a follow-up report from product quality group providing investigation results.
Updated information: investigation results.

Follow-up (10Jan2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Expiration date of device added.

Follow-up (20Jun2024): This is a spontaneous follow-up report received from Nurse, Program ID: (164974).
Updated information: dosing regimen

Follow-up (16May2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Event recoded to device mechanical issue

Follow-up (01Jul2025): This is a follow-up report from product quality group providing investigation results.

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

Mfr. Control Number: PV202400082066

ADDITIONAL INFORMATION

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; Regimen #2	0.6 mg, daily; Unknown	Unknown	MAR-2022 / Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # W131}; Regimen #1	0.6 mg, daily; Unknown	Unknown	MAR-2022 / Unknown; Unknown