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		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		13 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)

2 days of not injecting him/and it's been four days without my son being able to receive the hormone [Drug dose omission by device]
caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work [Wrong technique in device usage process]
it is damaged [Device defective]
caregiver wasted a dose of medication trying to figure out how to fix it [Device leakage]
the pen, had a low battery, so the dose indicator did not appear on the screen [Device image display issue]

(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 # KC8721; Exp.Dt. JAN-2027}
#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) 1.4 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.
PV202500052615

24c. DATE RECEIVED BY MANUFACTURER
25-JUN-2025

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

DATE OF THIS REPORT
01-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

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 13-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: KC8721, Expiration Date: Jan2027) at 1.4 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: DRUG DOSE OMISSION BY DEVICE (non-serious), described as "2 days of not injecting him/and it's been four days without my son being able to receive the hormone"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), described as "caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work"; DEVICE DEFECTIVE (non-serious), described as "it is damaged"; DEVICE LEAKAGE (non-serious), described as "caregiver wasted a dose of medication trying to figure out how to fix it"; DEVICE INFORMATION OUTPUT ISSUE (non-serious), described as "the pen, had a low battery, so the dose indicator did not appear on the screen". The action taken for somatropin was temporarily withdrawn.

Causality for "2 days of not injecting him/and it's been four days without my son being able to receive the hormone", "caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work", "it is damaged", "caregiver wasted a dose of medication trying to figure out how to fix it" and "the pen, had a low battery, so the dose indicator did not appear on the screen" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 25Jun2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site Investigation (Pfizer manufacturing site) -Battery Died Before Expiry/Display Not Functioning: The complaint for "dose indicator does not 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(s) 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. Site Investigation (Pfizer manufacturing site) - Delivery System Damage/Defect Not Classified: The complaint for "the device is damaged, it makes a mistake" 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, Loss of Function, 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 (INX#100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented. MDCP Investigation Summary and Conclusion: This complaint of "the patient's caregiver stated his son's pen got damaged, that they would send someone and replace the pen. Additionally, caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work. It's been 2 days since she last injected him. The patient's mother reported that the pen got damaged, it shows an error and the error won't go away. She stated it's been four days without my son being able to receive the hormone, and she urgently need to resolve this.", for GENOTROPIN PEN 12 was investigated.

Additional information: The patient's caregiver stated his son's pen got damaged, that they would send someone and replace the pen. Additionally, caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work. It's been 2 days since she last injected him. The patient's mother reported that the pen got damaged, it shows an error and the error won't go away. She stated it's been four days without my son being able to receive the hormone, and she urgently need to resolve this. On 02May2025, the nurse indicated that what was reported was that the device, the pen, had a low battery, so the dose indicator did not appear on the screen. Nurse explained to the patient's mother how to use the pen without needing to see the dose on the screen, but she indicated that they wanted a new pen. On 03May2025, patient's mother stated that all of this was a waste of time. In fact, the same guy told to the patient's mother that if he had known it was this over the phone, he would have resolved it. It was a waste of time for both. The pen just had a low battery, patient's mother don't even know why, because theoretically it should last until 2027. He couldn't even provide to the patient's mother what she needed, which is a new pen. Patient's mother still without the pen, the nurse was of no help, and her son is still without the hormone. Patient's mother dealing with this for a week.

Follow-up (02May2025 and 03May2025): This is a follow-up report from a Nurse, Program ID: 164974. Updated information: new event added (the pen, had a low battery, so the dose indicator did not appear on the screen) and clinical course.

Follow-up (21Jun2025): Follow-up attempts are completed.

Follow-up (25Jun2025): This is a follow-up report from product quality group providing investigation results.