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	DOMINICAN REPUBLIC		PRIVACY		13 Years	Male	Unk		Unk	

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

I cannot give him the dose that the doctor imposed because it does not mark it on the screen [No image display on device]
I cannot give him the dose that the doctor imposed because it does not mark it on the screen [Drug dose omission by device]
It gets stuck sometimes [Resistance to movement in device]
the device is expired / I cannot give him the dose that the doctor imposed because it does not mark it on the screen / the pen stopped working. [Device battery issue]
the device is expired [Expired device used]

(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) 1.8 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.
PV202500051816

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

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

DATE OF THIS REPORT
25-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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), first regimen (Batch/Lot number: unknown) at 1.8 mg daily, second regimen (Batch/Lot number: unknown) at 1 mg daily and third regimen (Batch/Lot number: unknown, Expiration Date: Jun2025) at 1.6 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: DEVICE INFORMATION OUTPUT ISSUE (non-serious), DRUG DOSE OMISSION BY DEVICE (non-serious), outcome "unknown" and all described as "I cannot give him the dose that the doctor imposed because it does not mark it on the screen"; DEVICE PHYSICAL PROPERTY ISSUE (non-serious), outcome "unknown", described as "It gets stuck sometimes"; DEVICE POWER SOURCE ISSUE (non-serious), outcome "unknown", described as "the device is expired / I cannot give him the dose that the doctor imposed because it does not mark it on the screen / the pen stopped working."; EXPIRED DEVICE USED (non-serious), outcome "unknown", described as "the device is expired".

Additional information: Reporter states that he noted the device was expired because 1 month ago (Apr2025) the pen stopped working.

Causality for "i cannot give him the dose that the doctor imposed because it does not mark it on the screen", "it gets stuck sometimes", "the device is expired / i cannot give him the dose that the doctor imposed because it does not mark it on the screen / the pen stopped working." and "the device is expired" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 20Jun2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site Investigation: Device Investigation: Injection Device Blocked/Cannot Set Dose/Deliver Dose/Injection Knob/Plunger Does Not/Never Moved The complaint for ''Sometimes gets stuck'' 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. Device Investigation: Device/Combination Product Used After Expiration. The complaint for ''dose doesn't show 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 W131. The reported defect is not representative of the quality of the batch.
Product Quality Group provided investigational summary and conclusion on 20Jun2025 for SOMATROPIN (DEVICE CONSTITUENT): MDCP Investigation Summary and Conclusion: The complaint of "I cannot give him the dose that the doctor imposed because it does not mark it on the screen... It gets stuck sometimes...he noted the device was expired because 1 month ago (Apr2025) the pen stopped working,." Genotropin pen was investigated by the manufacturing site. Site Investigation (Puurs): Device Investigation: Injection Device Blocked/Cannot Set Dose/Deliver Dose/Injection Knob/Plunger Does Not/Never Moved The complaint for "Sometimes gets stuck" 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. Device Investigation: Device/Combination Product Used After Expiration The complaint for "dose doesn't show 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 W131. The reported defect is not representative of the quality of the batch.

Follow-up (14Jun2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Follow-up (20Jun2025): This is a follow-up report from product quality group providing investigation results.

Batch/lot number is not provided, and it cannot be obtained.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Follow-up(20Jun2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Device expiration date and Investigation results updated.

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	1 mg, daily; Unknown	Unknown	Unknown; Unknown
#1) Genotropin Pen (SOMATROPIN) Solution for injection {Exp.Dt. JUN-2025}; Regimen #3	1.6 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # W131}; Regimen #1	; Unknown	Unknown	Unknown; Unknown