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		4 Years	Female	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)

Pen is expired and is having issues [Device defective]

Case Description: The initial case was missing the following minimum criteria: Adverse event.

(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 {Lot # FH2003; Exp.Dt. APR-2024}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # W151}

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

15. DAILY DOSE(S)
#1) 0.7 mg, daily
#2)

16. ROUTE(S) OF ADMINISTRATION
#1) Subcutaneous
#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)
#1) Unknown
#2) Unknown

19. THERAPY DURATION
#1) 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	Relevant Med History	none ()

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.
PV202500054735

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

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

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

DATE OF THIS REPORT
28-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 4

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Upon receipt of follow up information on 07May2025, this case now contains all required information to be considered valid.

This is a spontaneous report received from a Nurse and a Consumer or other non HCP from product quality group, Program ID: 164974.

A 4-year-old female patient received somatropin (GENOTROPIN PEN), (Lot number: FH2003, Expiration Date: Apr2024) at 0.7 mg daily, subcutaneous, Device Lot Number: W151, Device Expiration Date: 30Apr2024. The patient had no relevant medical history. The patient's concomitant medications were not reported.
The following information was reported: DEVICE DEFECTIVE (non-serious), outcome "unknown", described as "Pen is expired and is having issues".

Additional Information: Pen is expired and is having issues. Through the lot of the box (FH2003), it was possible to verify that the pen belongs to lot W151. As of 04Jun2025, reporter stated the pen is expired since last year but the hospital won't change it until it stops working.

Product Quality Group provided investigational results on 23Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site investigation (Pfizer Manufacturing Site): Container Leaking During Prep/Use. The complaint for "the liquid leaks" 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 W151. The reported defect is not representative of the quality of the batch. Site investigation (Puurs): Non-Defect/Personal Preference Not Classified. The complaint for "I found out that the pen has an expiration date - it expired last year" of Genotropin Pen Injectable was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of reference sample and 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 "W151". The reported defect is not representative of the quality of the batch. Device Investigation: The complaint occurred on 05May2025, after the expiry date of 30Apr2024; hence, the product was expired during use. There is no evidence that the device constituent part did not perform as expected during its defined shelf-life. As such, this device engineering investigation should be cancelled.

Product Quality Group provided investigational results on 24Jul2025 for somatropin (device constituent): Medical Device Combination Product Investigation Summary and Conclusion: This complaint of the nurse reported that the pen has expired and is experiencing some failure. The nurse did not remember the presentation of the device, she only indicated that it was 'purple', however the report was issued with the presentation 5.3mg, according to the system. According to the nurse's description (purple) and the presentation informed in the initial case, the presentation will be kept as Genotropin 12 mg for Genotropin Pen was investigated by the site.

Causality for "pen is expired and is having issues" was determined associated to device constituent of somatropin (malfunction).

Follow-up (14May2025): This is a spontaneous report received from a Nurse and a Consumer or other non HCP from product quality group.
Updated information: device lot number, expired device used deleted.

Follow-up (04Jun2025): This is a spontaneous follow-up report received from a Consumer or other non-HCP, Program ID: (164974).
Updated information includes: additional information.

Follow-up (01Jul2025): This is a spontaneous follow-up report received from a Consumer or other non-HCP, Program ID: (164974).
Updated information included: relevant medical history, lot number and expiry date, route of administration.

Follow-up (23Jul2025 and 24Jul2025): This is a spontaneous follow-up report from product quality.
Updated information: Batch and lot tested and found within specifications and investigation results.