SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		4 Years	Female	Unk		Unk	

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)

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 # 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
01-JUL-2025

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

DATE OF THIS REPORT
09-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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: Apr2024. 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".

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

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.

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..