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	COSTA RICA		PRIVACY		Unk	Unk	Unk		Unk		

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

The hormone tube was defective [Device defective]

Case Description: This is a spontaneous report received from a Pharmacist from product quality group.

A patient (age and gender not provided) received somatropin (GENOTROPIN PEN), (Lot number: HN2503, Expiration Date: 31Aug2026).

(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 # HN2503; Exp.Dt. 31-AUG-2026}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK	#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.
202500113334

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

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

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

DATE OF THIS REPORT
28-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE DEFECTIVE (non-serious), outcome "unknown", described as "The hormone tube was defective".

Product Quality Group provided investigational results on 22Jul2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site investigation (Pfizer Manufacturing Site): The complaint for "The hormone tube was defective." of "Genotropin Dual Injectable" and "Genotropin Pen Injectable" was investigated. The investigation included reviewing the involved batch records, deviation investigation, pictures of complaint sample, evaluation of reference sample, an analysis of the complaint history for the involved scope and Annual Product Review for the cartridge. The investigation included reviewing Annual Product Review for the U2 pen. Quantity of returned complaint samples: 2 pictures. The reported defect was not present on the returned pictures. 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 "HN2503" and for the pen no lot was available. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution.

Causality for "the hormone tube was defective" was determined associated to device constituent of somatropin (malfunction).

No follow-up attempts are possible. Batch/lot number is not provided, and it cannot be obtained.

Follow-up (22Jul2025): This is a follow-up report from product quality group providing investigation results.
Updated information included: Suspect drug details (action taken updated to not applicable) and Investigation results.

No follow-up attempts are possible. Batch/lot number is not provided, and it cannot be obtained.