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	DOMINICAN REPUBLIC		PRIVACY		10 Years	Male	Unk	14	JUL	2025	

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

The Pen did not work, it did not let her insert the medication [Device defective]

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 10-year-old male patient received somatropin (GENOTROPIN PEN), since Jul2025 (Batch/Lot number: unknown) at 1.4 mg 1x/day. The patient's relevant medical history and concomitant medications were not reported.

(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 for injection

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.4 mg, 1x/day	#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) JUL-2025 / 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.
PV202500086135

24c. DATE RECEIVED BY MANUFACTURER
01-AUG-2025

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

DATE OF THIS REPORT
06-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

The following information was reported: DEVICE DEFECTIVE (non-serious) with onset 14Jul2025, outcome "unknown", described as "The Pen did not work, it did not let her insert the medication".

The reporter considered "The Pen did not work; it did not let her insert the medication" not related to somatropin. Causality for "The Pen did not work, it did not let her insert the medication" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 01Aug2025 for somatropin (device constituent): Manufacturing site investigation: No further investigation was required as no valid lot number or returned sample was available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue "Loss of Function" was selected as the device did not work and did not let her apply the medication. Since the issue with the pen is not clear, the reported issue will be interpreted as Loss of function. 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 (document INX100281795, version 9.0). All complaint investigations are trended. There is no current trend alert documented.

Additional information: The patient's mother reported that she began Genotropin treatment last week, in Jul2025. On 14Jul2025, when she changed the medication inside the Pen, the Pen did not work, and it did not let her insert the medication. As of 16Jul2025, the nurse reported that there was an improper handling of the device by the patient's mother.

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

Follow-up (16Jul2025): This is a spontaneous follow-up report received from a Nurse. Updated information: New reporter. Dosage regimen, new event.

Follow-up (01Aug2025): This is a follow-up report from product quality group providing investigation results. Updated information: Somatropin start date. The event ''Device issue'' was re-coded to ''Device defective''. Onset date of event added. The event ''Wrong technique in device usage process'' was removed.