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	GUATEMALA		PRIVACY		13 Years	Male	Unk		Unk	

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

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

started applying the dose, but it did not mark point 2,4 and 6 [Poor quality device used]

Case Description: This is a spontaneous report received from a Consumer or other non HCP from product quality group.

A 13-year-old male patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 1.6 mg daily (1.6 mg, daily (every 24 hours)). The patient's relevant medical history and concomitant medications were not reported.

(Continued on Additional Information Page)

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) 1.6 mg, daily (every 24 hours)	#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.
202500078495

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

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

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

DATE OF THIS REPORT
23-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The following information was reported: POOR QUALITY DEVICE USED (non-serious), described as "started applying the dose, but it did not mark point 2,4 and 6". The action taken for somatropin was unknown.

Causality for "started applying the dose, but it did not mark point 2,4 and 6" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 15Apr2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site Investigation (Puurs): 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, Unable/Difficult to Set/Draw Dose, was reported. 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 (INX# INX100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented. MDCP Investigation Summary and Conclusion: The complaint of The patient's mother says, ''I followed all the instructions, I went back to the cartridge because I was going to do the change and when started charging, as it was already loaded and I started applying the dose, but it did not mark point 2, 4 and 6, I could not do the procedure again, I think it is something from the device" for Genotropin U2 Pen was received.

Follow-up (15Apr2025): This is a follow-up report from product quality group providing investigational results.
Updated information: Product details (dose, frequency and dose description updated).
Follow-up (23May2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.