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		15 Years	Female	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)

the trigger button doesn't work well [Device mechanical jam]
device was not working [Device defective]
Yesterday we couldn't give the girl the medication [Drug dose omission by device]

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

A 15-year-old female patient received somatropin (GENOTROPIN PEN),

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Genotropin Pen (SOMATROPIN) Solution for injection {Lot # LR7825; Exp.Dt. MAY-2027}
#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) 2 mg, daily (every night)	#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.
PV202400136352

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

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

DATE OF THIS REPORT
21-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 6

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

(Lot number: LR7825, Expiration Date: May2027) at 2 mg daily (2 mg, daily (every night)). The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE MECHANICAL ISSUE (non-serious), described as "the trigger button doesn't work well"; DEVICE DEFECTIVE (non-serious), described as "device was not working"; DRUG DOSE OMISSION BY DEVICE (non-serious), described as "Yesterday we couldn't give the girl the medication". The action taken for somatropin was unknown.

Causality for "the trigger button doesn't work well", "device was not working" and "yesterday we couldn't give the girl the medication" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 28Nov2024, 02Mar2025 and 16May2025 for somatropin (device constituent): Investigation Summary and Conclusion: 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, Injection Knob/Dial Issue and Loss of Function were 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 (INX100281795), Version (9.0). All complaint investigations are trended. There is not a current trend alert documented.

Additional Information: On 28Apr2025, the patient's caregiver indicated that the device was not working and mentioned that they were on a cruise. A virtual consultation was offered, but the patient's mother requested a prescription to give to the ship's staff to see if they had any needles.

Follow-up (28Nov2024): This is a follow-up report from product quality group providing investigation results.

Follow-up (02Mar2025): This is a follow-up report from product quality group providing investigation results.

Follow-up (28Apr2025): This is a follow-up report from received from a Consumer or other non HCP, Program ID: 164974.
Updated information: new reporters, new event added ("device was not working"), product details (dosage regimen, drug lot number and drug expiration date) and clinical course.

Follow-up (07May2025): This is a follow-up report from product quality group.
Updated information: device details (medical device component code).

Follow-up (16May2025): This is a spontaneous follow-up report from product quality group.
Updated information: investigation results