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		5 Years	Male	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 device is giving me problems, but it is not going down [Device mechanical jam]
The dosage that the doctor prescribed is 0.68 mg and she gives him 0.8 mg [Drug dose prescribing error]

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

A 5-year-old male patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 0.8 mg daily.

(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) 0.8 mg, daily	#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.
PV202500045594

24c. DATE RECEIVED BY MANUFACTURER
02-JUN-2025

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

DATE OF THIS REPORT
05-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

NAME AND ADDRESS WITHHELD.

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 MECHANICAL ISSUE (non-serious), described as "The device is giving me problems, but it is not going down"; PRODUCT PRESCRIBING ERROR (non-serious), described as "The dosage that the doctor prescribed is 0.68 mg and she gives him 0.8 mg". The action taken for somatropin was unknown.

The reporter considered "the device is giving me problems, but it is not going down" not related to somatropin. Causality for "the device is giving me problems, but it is not going down" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 06May2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site Investigation (Pfizer Manufacturing Site): 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. Two distinct Complaint Issues of "Injection Knob/Dial Issue" and "Excess Dose" were reported. However, these two distinct Complaint Issues map to same Hazard/Hazardous Situation. 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# 100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Additional information: The patient's assistant states: "The problem is that the device I use to inject the child is giving me problems, but it is not going down. I need to program them so they can check the pen to see if it's defective or if I'm doing it wrong." She also mentions that the dosage the doctor prescribed is 0.68 mg, and she gives him 0.8 mg.

Product Quality Group provided investigational results on 02Jun2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: The complaint of the device I use to inject the child is giving me problems, but it is not going down. I need to program them so they can check the pen to see if it's defective or if I'm doing it wrong for GENOTROPIN Pen was investigated by the manufacturing site.

Follow-up (06May2025): This is a follow-up report from product quality group providing investigation results.

Follow-up (24May2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Follow-up (02Jun2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Causality for device mechanical jam updated to unrelated and investigation results added.