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		12 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)

when I do the needle change procedure and the movement as the nurse informed me, I give the first touch for him to discard the drop, and then it shows the numbering that show me more than the amount [Device use issue]
I should apply and the cartridge where the medication goes came loose/disconnected (where I put the needle), so I can put it [Device connection loose]

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

(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 # HL2024; Exp.Dt. 15-JUL-2026}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution **(Continued on Additional Information Page)**

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.6 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.
PV202500012659

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

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

DATE OF THIS REPORT
15-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 5

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

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 12-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: HL2024, Expiration Date: 15Jul2026) at 1.6 mg daily and second regimen (Batch/Lot number: unknown) at 1 mg daily, Device Expiration Date: 31Dec2026. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE USE ISSUE (non-serious), described as "when I do the needle change procedure and the movement as the nurse informed me, I give the first touch for him to discard the drop, and then it shows the numbering that show me more than the amount"; DEVICE CONNECTION ISSUE (non-serious), described as "I should apply and the cartridge where the medication goes came loose/disconnected (where I put the needle), so I can put it". The action taken for somatropin was unknown.

Causality for "when i do the needle change procedure and the movement as the nurse informed me, i give the first touch for him to discard the drop, and then it shows the numbering that show me more than the amount" and "i should apply and the cartridge where the medication goes came loose/disconnected (where i put the needle), so i can put it" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 26Feb2025 for somatropin (device constituent): 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. The Complaint Issue, Cartridge/Holder Loose, 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 (INX100281795), Version (9.0). All complaint investigations are trended. There is no current trend alert documented.

Product Quality Group provided investigational results on 31Mar2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: This complaint for The patient assistant says, "I need someone to help me, when I do the needle change procedure and the movement as the nurse informed me, I give the first touch for him to discard the drop, and then it shows the numbering that show me more than the amount I should apply and the cartridge where the medication goes came loose/disconnected (where I put the needle), so I can put it. for Genotropin/Genotonorm U2 Pen was investigated by the manufacturing site.

Product Quality Group provided investigational results on 08May2025 for somatropin (device constituent): 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. The Complaint Issue, Injection Knob/Dial Issue, was reported. The Issue of, Cartridge/Holder Loose, was already investigated under INV-335482. 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). Additional Complaint Issues of Unable/Difficult to Set/Draw Dose was reported. This Complaint Issue is considered a cascading event. All complaint investigations are trended. There is no current trend alert documented.

Additional information: As of 03Apr2025, reporter stated they finished setting the device and when they tried to dial 0.4 mg it did not dial, also stated that when setting the numbers on the device was getting a bit hard (it was not light). As of 05Apr2025, nurse reported that the patient's mother complaint about the pen's button not working properly, but nurse stated this was not true as she checked it and everything was working normally, it was just a bit hard to press the button but it was normal.

Follow-up (26Feb2025): This is a spontaneous follow-up report received from product quality group. Updated information: investigation results.
Follow-up (19Mar2025): Follow-up attempts are completed.
Follow-up (31Mar2025): This is a follow-up report from the product quality group. Updated information included: investigation results, action taken and expiration date.
Follow-up (03Apr2025): This is a spontaneous follow-up report received from a Consumer or other non-HCP, Program ID: (164974). Updated information includes new events of device mechanical issue, device physical property issue and device difficult to use.
Follow-up (05Apr2025): This is a spontaneous follow-up report received from a Nurse, Program ID: (164974). Updated information: Dosage regimen, Device expiration date, clinical course.
Follow-up (15Apr2025): This is a follow-up report from the product quality group. Updated information included: event removed (Resistance to movement in device, Device difficult to use and Device mechanical jam).
Follow-up (08May2025): This is a follow-up report from product quality group providing investigation result
Follow-up (15May2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION

Mfr. Control Number: PV202500012659

ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Genotropin Pen (SOMATROPIN) Solution for injection; Regimen #2	1 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection; Regimen #1	; Unknown	Unknown	Unknown; Unknown