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	PANAMA		PRIVACY		8 Years	Female	Unk		Unk	

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

tell me that it hurts [Injection site pain]
handled it poorly when loading the new vial, since they did not return the plunger [Wrong technique in device usage process]
Yesterday I couldn't give them the medicine because the yellow pen turns very hard [Drug dose omission by device]
It's hard for me to use it [Device difficult to use]
My needles have been damaged [Device component defective]
turns with great difficulty [Device mechanical jam]
numbers are no longer visible, so the dose is unknown [Device image display issue]

(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 {Lot # A143}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1 mg, daily #2) UNK	#1) Unknown #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 #2) Unknown	#1) 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.
PV202300195974

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

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

DATE OF THIS REPORT
30-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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

threw away about 80% of the medicine [Device leakage]
threw away about 80% of the medicine [Inaccurate delivery by device]

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

An 8-year-old female patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 1 mg daily, Device Lot Number: A143, Device Expiration Date: May2025. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: INJECTION SITE PAIN (non-serious), outcome "unknown", described as "tell me that it hurts"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), outcome "unknown", described as "handled it poorly when loading the new vial, since they did not return the plunger"; DRUG DOSE OMISSION BY DEVICE (non-serious), outcome "unknown", described as "Yesterday I couldn't give them the medicine because the yellow pen turns very hard"; DEVICE DIFFICULT TO USE (non-serious), outcome "unknown", described as "It's hard for me to use it"; DEVICE ISSUE (non-serious), outcome "unknown", described as "My needles have been damaged"; DEVICE MECHANICAL ISSUE (non-serious), outcome "unknown", described as "turns with great difficulty"; DEVICE INFORMATION OUTPUT ISSUE (non-serious), outcome "unknown", described as "numbers are no longer visible, so the dose is unknown"; DEVICE LEAKAGE (non-serious), DEVICE DELIVERY SYSTEM ISSUE (non-serious), outcome "unknown" and all described as "threw away about 80% of the medicine". The action taken for somatropin and somatropin was unknown.

Additional information: Nurse mentioned that the patient had difficulty with the Pen, because they handled it poorly when loading the new vial, since they did not return the plunger, but the Pen works very well. Upon follow-up on 16Apr2025: Patient's mother reported that she has the pen since 2023. As of 15Apr2025, nurse stated the device turned with difficulty, a bit of strength had to be applied so the dose could be set.

Product Quality Group provided investigational results on 15Jan2024 for somatropin (device constituent): Conclusion: The complaint for "patient had difficulty with the pen - they didn't return the plunger of GENOTROPIN PEN INJECTABLE was investigated. The investigation included reviewing an analysis of the complaint history for the product type and Annual Product Review. The final scope was determined to be the reported product and product type, as no lot was available. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability and patient safety. PGS Puurs concludes that the reported defect is not representative of the Pfizer Puurs process quality and remains acceptable. The NTM process determined that no regulatory notification was required. The reported defect could not be confirmed. No root cause or CAPA were identified as the complaint was not confirmed.

Product Quality Group provided investigational results on 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, Display Not Functioning, was reported. The issues of Injection Knob/Dial Issue, Needle Bent/Broken and Leaking During Prep/Use were reported in this DEI INV-351592. 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.

Causality for "handled it poorly when loading the new vial, since they did not return the plunger", "yesterday i couldn't give them the medicine because the yellow pen turns very hard", "it's hard for me to use it", "my needles have been damaged", "turns with great difficulty", "numbers are no longer visible, so the dose is unknown" and "threw away about 80% of the medicine" was determined associated to device constituent of somatropin (malfunction).

Amendment: This follow-up report is being submitted to amend previously reported information: Suspect drug Genotropin was updated and malfunction field was populated.

Amendment: This follow-up report is being submitted to amend previous information: To amend suspect drug updated to Genotropin pen.

Follow-up (15Jan2024): This is a spontaneous follow-up report from product quality complaint providing investigation results.

Amendment: This follow-up report is being submitted to allow appropriate reporting to health authorities.

Follow-up (15Apr2025): This is a spontaneous follow-up report received from a Consumer or other non HCP, Program ID: 164974.

Updated information: Reporter tabs updated. Dosage regimen tab updated. New events: Drug dose omission by device, Device damage, Device mechanical jam, Device image display issue, Injection site pain and Device leakage

Follow-up (16Apr2025): This is a spontaneous follow-up report received from a Consumer or other non HCP, Program ID: 164974.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Updated information: New event: Device difficult to use

Follow-up (15Apr2025): This is a spontaneous follow-up report received from a Nurse, Program ID: 164974. Updated information: device lot number added, VT "handled it poorly when loading the new vial, since they did not return the plunger" recoded to "wrong technique in device usage process", additional information.

Amendment (PSSR): This follow-up report is being submitted to amend previous information: to remove At Risk classification.

Follow-up (16May2025): This is a follow-up report from product quality group.
Updated information: new event added (Inaccurate delivery by device), event details ("Device damage" recoded to "Device component defective") and investigation results.
Follow-up (30May2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.