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)

handled it poorly when loading the new vial, since they did not return the plunger [Device use error]
Yesterday I couldn't give them the medicine because the yellow pen turns very hard [Drug dose omission by device]
My needles have been damaged [Device damage]
turns with great difficulty [Device mechanical jam]
numbers are no longer visible, so the dose is unknown [Device image display issue]
tell me that it hurts [Injection site pain]
threw away about 80% of the medicine [Device leakage]

(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) 1 mg, daily	#1) Unknown
#2) UNK	#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.
PV202300195974

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

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

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

DATE OF THIS REPORT
21-APR-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

It's hard for me to use it [Device difficult to use]

Case Description: The initial case was missing the following minimum criteria: adverse event. Upon receipt of follow-up information on 30Nov2023, this case now contains all required information to be considered valid.

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. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE USE ERROR (non-serious), described as "handled it poorly when loading the new vial, since they did not return the plunger"; DRUG DOSE OMISSION BY DEVICE (non-serious), described as "Yesterday I couldn't give them the medicine because the yellow pen turns very hard"; DEVICE PHYSICAL PROPERTY ISSUE (non-serious), described as "My needles have been damaged"; DEVICE MECHANICAL ISSUE (non-serious), described as "turns with great difficulty"; DEVICE INFORMATION OUTPUT ISSUE (non-serious), described as "numbers are no longer visible, so the dose is unknown"; INJECTION SITE PAIN (non-serious), described as "tell me that it hurts"; DEVICE LEAKAGE (non-serious), described as "threw away about 80% of the medicine"; DEVICE DIFFICULT TO USE (non-serious), described as "It's hard for me to use it". The action taken for somatropin and somatropin was unknown.

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", "my needles have been damaged", "turns with great difficulty", "numbers are no longer visible, so the dose is unknown", "threw away about 80% of the medicine" and "it's hard for me to use it" was determined associated to device constituent of somatropin (malfunction).

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.

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.

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.

Updated information: New event: Device difficult to use