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	COSTA RICA		PRIVACY		12 Years	Female	Unk		Unk		

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

it failed again exactly the same as the previous time/it made him waste more or less half of the Genotropin cartridge [Device leakage]

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

A 12-year-old female patient (unknown if pregnant) 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.
202500045397

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

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

DATE OF THIS REPORT
01-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 5

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 LEAKAGE (non-serious), described as "it failed again exactly the same as the previous time/it made him waste more or less half of the Genotropin cartridge". The action taken for somatropin was unknown.

Causality for "it failed again exactly the same as the previous time" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 28Mar2025 for somatropin (device constituent): 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, Leaking During Loading, 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.

Additional information: Patient's father indicated he had already reported that the pen was failing, they already came to check it, they confirmed that it was failing about 15 days ago (Feb2025), patient ran out of Genotropin so they bought a new one on 23Feb2025, he put it back in and it failed again exactly the same as the previous time and it made him waste more or less half of the Genotropin cartridge, it was left half of the dose of Genotropin in caregiver hands, at the moment of placing the cartridge the whole push device goes up. The pharmacy manager explained the situation about the damage of 2 Genotropin devices with a patient.

The information on the batch/lot number for somatropin will be requested and submitted if and when received.

Follow-up (18Mar2025): This is a spontaneous follow-up report received from a Consumer or other non HCP and an Other HCP from product quality group, Program ID: 164974.
Updated information: New event added: "Product storage error"

Follow-up (28Mar2025): This is a follow-up report from product quality group providing investigation results. Updated information includes investigation results, device issue recoded to device leakage.

Amendment (PSSR): This follow-up report is being submitted to amend previous information: to remove event "yesterday we left the medicine outside, we left it unrefrigerated" (LLT " Product storage error").

Follow-up (17Apr2025): This is a follow-up report from product quality group.
Updated information: FDA codes added.
Follow-up (01May2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.