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		10 Years	Male	Unk	07	APR	2025	

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

The pen leaked a little bit of medicine because she was doing the procedure wrong [Wrong technique in device usage process]
the liquid leaked out [Device leakage]

Case Description: The initial case was missing the following minimum criteria: adverse event. Upon receipt of follow-up information on 09Apr2025, this case now contains all required information to be considered valid.

This is a spontaneous report received from a Consumer or other non HCP and a Nurse 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 # NK3098; Exp.Dt. 15-FEB-2027}
#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)	#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.
PV202500042984

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

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

DATE OF THIS REPORT
13-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 10-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: NK3098, Expiration Date: 15Feb2027) at 1 mg daily. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE LEAKAGE (non-serious) with onset 07Apr2025, described as "the liquid leaked out"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), described as "The pen leaked a little bit of medicine because she was doing the procedure wrong". The action taken for somatropin was unknown.

Causality for "the pen leaked a little bit of medicine because she was doing the procedure wrong" and "the liquid leaked out" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 28Apr2025 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. DEI: 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 not a current trend alert documented.

Additional information: A patient representative explained that it turned out that yesterday (07Apr2025), when they changed the ampoule for the first time, one of them broke. It did not break, but the liquid leaked out. The glass itself did not break; they changed two ampoules, and what it did was leak the liquid. On 09Apr2025, the nurse indicated that the patient had doubts since when she inserted the needle into the pen, the pen leaked a little bit of medicine because she was doing the procedure wrong, and then it was clarified to her and later she understood better.

Follow-up (28Apr2025): This is a spontaneous follow-up report from product quality group.
Updated information: expiration date and investigation results.

Follow-up (08May2025): This is a follow-up report from product quality group providing investigation results. updated information includes Device available for evaluation field updated.