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	DOMINICAN REPUBLIC		PRIVACY		11 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)

he device leaked medication when first inserted and the dosage was incorrect [Device leakage]
the patient was supposed to get a dose of 10, but when she was turning the vial of the device, she realized that it only showed up to 3. [Inaccurate delivery by device]
she had a bad practice in administering the medication [Wrong technique in device usage process]
when first inserted and the dosage was incorrect [Incorrect dose administered by device]

(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(at night)	#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.
PV202500086110

24c. DATE RECEIVED BY MANUFACTURER
07-AUG-2025

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

DATE OF THIS REPORT
12-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

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

An 11-year-old female patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 1 mg daily (1 mg, daily(at night)). The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE LEAKAGE (non-serious), described as "he device leaked medication when first inserted and the dosage was incorrect"; DEVICE DELIVERY SYSTEM ISSUE (non-serious), described as "the patient was supposed to get a dose of 10, but when she was turning the vial of the device, she realized that it only showed up to 3."; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), described as "she had a bad practice in administering the medication"; INCORRECT DOSE ADMINISTERED BY DEVICE (non-serious), described as "when first inserted and the dosage was incorrect". The action taken for somatropin was unknown.

Product Quality Group provided investigational summary and conclusion on 29Jul2025 for somatropin (device constituent): Site Investigation (PUURS): 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 Prep/Use, 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 (INX#100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Additional information: The patient's mother indicated that on the first day of the injection the medication spilled a little. The main problem occurred on the fifth day, when she went to administer the dose, she explained that the patient was supposed to get a dose of 10, but when she was turning the vial of the device, she realized that it only showed up to 3. Her consultation was to know what he should do in that situation. Reporter indicated that: "She was asking a question to the previous lady, since she had a bad practice in administering the medication." Reporter indicated that the device leaked medication when first inserted and the dosage was incorrect.

Causality for "he device leaked medication when first inserted and the dosage was incorrect", "the patient was supposed to get a dose of 10, but when she was turning the vial of the device, she realized that it only showed up to 3.", "she had a bad practice in administering the medication" and "when first inserted and the dosage was incorrect" was determined associated to device constituent of somatropin (malfunction).

Follow-up(29Jul2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Investigation results updated.

Follow-up (07Aug2025): This is a follow-up report from product quality group providing investigation results. Updated information includes investigation codes updated.