SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		6 Years	Male	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 spilled half of it [Device leakage]
pen broke, it jammed [Device handling error]
the patient uses the 5.3 mg version, but they were given the 12 mg one [Device dispensing error]
patient should receive 6 mg, and other days 8 mg [Drug prescription issue]

Case Description: The initial case was missing the following minimum criteria: Adverse event. Upon receipt of follow up information on 21Jul2025, this case now contains all required information to be considered valid.

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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 # LK3089; Exp.Dt. FEB-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # L092}

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.7 mg, daily	#1) Unknown
#2)	#2) Unknown

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

17. INDICATION(S) FOR USE
#1) Unknown
#2) Unknown

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#1) Unknown
#2) Unknown	#2) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

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.
PV202500088959

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

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

DATE OF THIS REPORT
13-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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

A 6-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: LK3089, Expiration Date: Feb2027) at 0.7 mg daily, Device Lot Number: L092. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE LEAKAGE (non-serious), described as "it spilled half of it"; DEVICE USE ERROR (non-serious), described as "pen broke, it jammed"; DEVICE DISPENSING ERROR (non-serious), described as "the patient uses the 5.3 mg version, but they were given the 12 mg one"; PRODUCT PRESCRIBING ISSUE (non-serious), described as "patient should receive 6 mg, and other days 8 mg". The action taken for somatropin was unknown.

Causality for "it spilled half of it", "pen broke, it jammed", "the patient uses the 5.3 mg version, but they were given the 12 mg one" and "patient should receive 6 mg, and other days 8 mg" was determined associated to device constituent of somatropin (malfunction).

Additional information: The patient's caregiver reports: "Six months ago, the Children's Hospital gave me the pen to inject the Genotropin hormone. On Saturday night, the pen broke, it jammed. I was changing to a new hormone cartridge, and it spilled half of it (it spilled when I was removing the air). The entire piston (button) came out, and the pen became extremely stiff. I called the Children's Hospital, and they told me they only provide pens during the week." The caregiver also mentions that they were given a completely different pen, as the patient uses the 5.3 mg version, but they were given the 12 mg one. They state that the doctor at the Children's Hospital prescribed the treatment as follows: some days the patient should receive 6 mg, and other days 8 mg. The caregiver was told the following at the hospital regarding the new pen: "We don't have any. Use this one if you want, and if not, just leave it." The caregiver expresses discomfort with this prescription, as it would require administering the medication multiple times using different devices for Genotropin. Upon follow-up on 08Aug2025: "The problem is that the children's hospital tells us there is no PEN and gives us another one, which I find very strange since you did help me".

Follow-up (08Aug2025): This is a spontaneous follow-up report received from a Consumer or other non HCP.

Updated information: Device breakage event recoded as Device handling error.