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		15 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)

trouble eating [Eating disorder]
always has an upset stomach [Upset stomach]
tolerates some foods and not others [Food intolerance]
The device got wet and stopped showing the dosage [Device moisture damage]
does not show it on the screen [No image display on device]

Case Description: The initial case was missing the following minimum criteria: adverse event. Upon receipt of follow-up information on 11Aug2025, this case now contains all required information to be considered valid.

(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 # LD7551; Exp.Dt. JAN-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D129}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.3 mg, 1x/day	#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.
PV202500097035

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

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

DATE OF THIS REPORT
14-AUG-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

This is a spontaneous report received from a Consumer or other non HCP and a Nurse, Program ID: 164974.

A 15-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: LD7551, Expiration Date: Jan2027) at 1.3 mg 1x/day, Device Lot Number: D129, Device Expiration Date: Jan2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: EATING DISORDER (non-serious), outcome "unknown", described as "trouble eating"; ABDOMINAL DISCOMFORT (non-serious), outcome "unknown", described as "always has an upset stomach"; FOOD INTOLERANCE (non-serious), outcome "unknown", described as "tolerates some foods and not others"; DEVICE PHYSICAL PROPERTY ISSUE (non-serious), outcome "unknown", described as "The device got wet and stopped showing the dosage"; DEVICE INFORMATION OUTPUT ISSUE (non-serious), outcome "unknown", described as "does not show it on the screen". The action taken for somatropin was unknown.

Causality for "the device got wet and stopped showing the dosage" and "does not show it on the screen" was determined associated to device constituent of somatropin (malfunction).

Additional Information: The patient's mother called and stated that she needed an appointment with the nurse because the GENOTROPIN PEN was malfunctioning and she needed the nurse to check it. On 08Aug2025, the nurse stated: "It was misuse of the device because the lady sent the child, who is already a bit older, around 14 years old, to his father with the medication, and they carried the GENOTROPIN device in a thermos with ice and water. The device got wet and stopped showing the dosage." On 11Aug2025 , the patient manager indicated: "They are going to change the device, because it is not marking the dose, I place it, but it does not show it on the screen, I am looking for a good pediatrician to check the girl, because the girl is giving me trouble eating, she is always has an upset stomach, she tolerates some foods and not others, however, I am going to see if the pediatrician indicates a specialist."