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		14 Years	Male	Unk			2025	

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

previously it was 1.5 mg, but we were administering 1.4 mg because 1.5 wasn't available [Drug dose prescribing error]
the dosage wasn't showing properly/device was not displaying the dosage [Device image display issue]
previously it was 1.5 mg, but we were administering 1.4 mg because 1.5 wasn't available [Incorrect dose administered by device]
submerged the device in a container with ice and water, left it in the water, and it stopped displaying [Product storage error]

Case Description: This is a spontaneous report received from a Consumer

(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 **(Continued on Additional Information Page)**

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.4 mg (prescribed 1.5 mg)	#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 / 2025	#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.
PV202500072400

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

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

DATE OF THIS REPORT
07-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 5

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

or other non HCP and a Nurse from product quality group, Program ID: 164974.

A 14-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) till 2025 at 1.4 mg (1.4 mg (prescribed 1.5 mg)), second regimen (Batch/Lot number: unknown) at 1 mg daily and third regimen (Batch/Lot number: unknown) at 2 mg daily, Device Lot Number: L207, Device Expiration Date: 31Oct2026. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PRODUCT PRESCRIBING ERROR (non-serious), INCORRECT DOSE ADMINISTERED BY DEVICE (non-serious) all with onset 2025 and all described as "previously it was 1.5 mg, but we were administering 1.4 mg because 1.5 wasn't available"; DEVICE INFORMATION OUTPUT ISSUE (non-serious) with onset 2025, described as "the dosage wasn't showing properly/device was not displaying the dosage"; PRODUCT STORAGE ERROR (non-serious), described as "submerged the device in a container with ice and water, left it in the water, and it stopped displaying". The action taken for somatropin was unknown.

Additional Information: Caregiver stated: "I was calling because I needed an applicator. I didn't know if it was due to humidity or something else, but I couldn't see the dosage". When asked about the dosage used, she explained: "The doctor had changed it. I was going to pick it up again. She had increased the dose to 2 mg; previously it was 1.5 mg, but we were administering 1.4 mg because 1.5 wasn't available. Now, I wasn't sure if the humidity from refrigeration was affecting it, but the dosage wasn't showing properly. At that moment, she wasn't administering it because she was planning to restart. She had been giving it based on what she believed was correct, turning the applicator as the nurse had previously instructed. But since around Holy Week, the dosage hadn't been visible. As the treatment was nearing its end, she decided to wait and see if the doctor would prescribe it again. After their appointment last week, when the doctor did prescribe it again, she decided to call to see if the device could be replaced. She also mentioned that if there was a pharmacy where she could buy it, she would do so without any problem". On 18Jun2025, the reporter stated that their answer was related to the sample being available, just do not know what they would use to administer the medication. Upon a follow-up received on 19Jun2025, patient's mother reported via email: "My answer is related to the sample being available, I just don't know what I would use to administer the medication". Then, regarding about missed doses: "Of course not, I was setting the doses based on the number of turns, but now the dose has been increased and I don't know how many turns that would be. In any case, I'll wait to see if the humidity settles". As of 26Jun2025, nurse indicated that the patient's mother submerged the device in a container with ice and water, left it in the water, and it stopped displaying. Upon a follow-up received on 26Jun2025, the patient's caregiver stated that the day before, a nurse had visited to check the ampoule applicator. The nurse informed her that she would report the issue so the device could be replaced. However, no one had contacted her since, and she was unsure how to administer the medication to the child, as the device was not displaying the dosage. Additionally, the caregiver mentioned that she used to inject 1.5 mg to the patient, and the treatment was intended to last for two months

Causality for "the dosage wasn't showing properly/device was not displaying the dosage", "previously it was 1.5 mg, but we were administering 1.4 mg because 1.5 wasn't available" and "submerged the device in a container with ice and water, left it in the water, and it stopped displaying" was determined associated to device constituent of somatropin (malfunction).

Follow-up (18Jun2025 and 19Jun2025): This is a spontaneous follow-up report received from a Consumer or other non HCP from product quality group. Updated information included: Product information (lot# and expiration date), event information (event Intentionally missed dose recoded to Drug dose omission by device, event Incorrect dose administered by device deleted), Clinical course details added.

Follow-up (19Jun2025): This is a spontaneous follow-up report received from product quality group.
Updated information: event removed ("At that moment, she wasn't administering it because she was planning to restart"), product details and clinical course.

Follow-up (26Jun2025): This is a spontaneous follow-up report received from reporter(s) Consumer. Updated information: Dosage regimen, new event (submerged the device in a container with ice and water, left it in the water, and it stopped displaying) and clinical course.

Follow-up (26Jun2025): This is a spontaneous follow-up report received from a Consumer.
Updated information: New event added (Incorrect dose administered by device), product details (dosage regimen) and clinical course.
Follow-up (07Aug2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Genotropin Pen (SOMATROPIN) Solution for injection; Regimen #2	1 mg, daily; Unknown	Unknown	Unknown; Unknown

Mfr. Control Number: PV202500072400

ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Genotropin Pen (SOMATROPIN) Solution for injection; Regimen #3	2 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # L207}; Regimen #1	; Unknown	Unknown	Unknown; Unknown