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	

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

It just marks three stripes and doesn't mark the dose applying [Device battery issue]
The device has three lines up and three lines down on the screen and does not dose the dose [Device image display issue]

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

An 11-year-old female patient received somatropin (GENOTROPIN PEN),

(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 # LR7825; Exp.Dt. MAY-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # W125}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.6 mg, every day (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.
PV202500086119

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

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

DATE OF THIS REPORT
07-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

(Lot number: LR7825, Expiration Date: May2027) at 0.6 mg 1x/day (0.6 mg, every day (at night)), Device Lot Number: W125, Device Expiration Date: Jan2024. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE POWER SOURCE ISSUE (non-serious), outcome "unknown", described as "It just marks three stripes and doesn't mark the dose applying"; DEVICE INFORMATION OUTPUT ISSUE (non-serious), outcome "unknown", described as "The device has three lines up and three lines down on the screen and does not dose the dose".

Additional information: Drug lot number: LR7825. Device lot number FF4160 (external) and W125 (internal). Reporter stated "I have a situation and I'd like to guide me, I have two cartridges that were the last ones that delivered me, but the device failed or I don't know what's going on, because it just marks three stripes and doesn't mark the dose applying. I called the PRIVACY distributor and they tell me they haven't received devices since January and they don't have a date to receive. I have a problem because I don't know how I can deliver the medication to the patient without the device and there is no chance to get a new one. I have two whole new cartridges and the girl from the distributor here at PRIVACY told me that she is recommending patients to switch to 5.3 mg instead of 12 mg, because she is not arriving in the country, I understand and I have no problem switching my medication, but the medication is expensive". Upon follow-up received on 04Aug2025, the nurse stated "The device has three lines up and three lines down on the screen and does not dose the dose. The pen has an expired date: Jan2024. Lot FF4160. Lot W125".

Causality for "it just marks three stripes and doesn't mark the dose applying" and "the device has three lines up and three lines down on the screen and does not dose the dose" was determined associated to device constituent of somatropin (malfunction).

Follow-up (04Aug2025): This is a spontaneous follow-up report received from a Nurse.
Updated information: suspect drug details (dosage regimen removed), new event added ("The device has three lines up and three lines down on the screen and does not dose the dose"), events details (event previously captured as "Device mechanical jam" removed; event recoded from "Device image display error" to "Device battery issue").