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		9 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)

The device was damaged, it is not indicating the dose and it does not inject [Device image display issue]
The device was damaged, it is not indicating the dose and it does not inject [Device defective]
the mother is not performing the right steps [Wrong technique in device usage process]

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

(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) 0.5 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.
202500042464

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

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

DATE OF THIS REPORT
11-APR-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.
NAME AND ADDRESS WITHHELD.
NAME AND ADDRESS WITHHELD.

Mfr. Control Number: 202500042464

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 9-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 0.5 mg 1x/day and second regimen (Batch/Lot number: unknown) at 0.9 mg 1x/day. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE INFORMATION OUTPUT ISSUE (non-serious), DEVICE DEFECTIVE (non-serious) and all described as "The device was damaged, it is not indicating the dose and it does not inject"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), described as "the mother is not performing the right steps". The action taken for somatropin was unknown.

The reporter considered "the device was damaged, it is not indicating the dose and it does not inject" and "the mother is not performing the right steps" not related to somatropin. Causality for "the device was damaged, it is not indicating the dose and it does not inject" and "the mother is not performing the right steps" was determined associated to device constituent of somatropin (malfunction).

Additional information: The device has been damaged, it is not indicating the dose and it is not injecting. Patient's mother indicates that she wants nursing advice because a month ago they changed her device to a new one and the new one no longer works, she indicates that it does not inject. On 27Feb2025: Nurse indicates: "The mother mentions that the device does not work, at the time of my evaluate and perform the step by step, everything works properly, it is because the mother is not performing the right steps"

Product Quality Group provided investigational results on 26Mar2025 for somatropin (device constituent): Site Investigation: 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. Two distinct Complaint Issues of ''Display Not Functioning'' and ''Injection Failure/Blocked'' were reported. ''Display Not Functioning'' maps to the Hazard/Hazardous Situation of ''H06-02 Hazard ''Electromagnetic Energy''/Hazardous Situation ''Non-functional electronics or LCD'' and ''Injection Failure/Blocked'' maps to the Hazard/Hazardous Situation of ''H10-01 Hazard ''Delivery Quantity''/Hazardous Situation ''Dose not administered (single) or delay of dose administration in pediatric/adult population''. 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 (INX100281795), Version (9.0). All complaint investigations are trended. There is no current trend alert documented.

The information on the batch/lot number for somatropin will be requested and submitted if and when received.

Follow-up (26Mar2025): This is a follow-up report from product quality group providing investigation results
Follow-up (11Apr2025): 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	0.9 mg, 1x/day; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection; Regimen #1	; Unknown	Unknown	Unknown; Unknown