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		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)

the dose adjustment button is "running" [Device leakage]
despite marking the dose, the button does not press on the substance/device used to administer the hormone to the girl was damaged/device was indeed damage [Device mechanical jam]
was unable to administer the medication. [Drug dose omission by device]

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.

(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 # LK3089; Exp.Dt. FEB-2027}
#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) 1.0 mg, daily	#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.
PV202500049362

24c. DATE RECEIVED BY MANUFACTURER
06-JUN-2025

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

DATE OF THIS REPORT
11-JUN-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.

Mfr. Control Number: PV202500049362

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

An 11-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: LK3089, Expiration Date: Feb2027) at 1 mg daily (1.0 mg, daily) and second regimen (Lot number: nk3089, Expiration Date: Feb2027) at 1 mg daily (1.0 mg, daily), Device Lot Number: A127, Device Expiration Date: 31Mar2025. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DRUG DOSE OMISSION BY DEVICE (non-serious), described as "was unable to administer the medication."; DEVICE LEAKAGE (non-serious), described as "the dose adjustment button is "running""; DEVICE MECHANICAL ISSUE (non-serious), described as "despite marking the dose, the button does not press on the substance/device used to administer the hormone to the girl was damaged/device was indeed damage". The action taken for somatropin was unknown.

Additional information: patient is afraid to apply the medication and lose the medication. She said the patient has already lost an entire cartridge because he was unable to administer the medication. Upon follow-up received on 22May2025, the patient's caregiver stated that the device used to administer the hormone to the girl was damaged. They made a video call with her, checked everything, and confirmed that the device was indeed damage, because when the cartridge was inserted, it didn't inject the dose.

Product Quality Group provided investigational results on 02Jun2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site Investigation (Pfizer Manufacturing Site) - Container Leaking During Prep/Use: The complaint for "cartridge that lost all medication" of "Genotropin Pen Injectable" was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of reference samples, an analysis of the complaint history for the involved scope and Annual Product Review. A complaint sample was not returned. The complaint is not confirmed. No root cause or CAPA were identified as the complaint was not confirmed. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability and patient safety. The Issue Escalation (NTM) process determined that no regulatory notification was required. The final scope was determined to be the associated lots of the reported lot A127. The reported defect is not representative of the quality of the batch. Site Investigation (Pfizer Manufacturing Site) - Delivery System Damage/Defect Not Classified: The complaint for "the dose adjustment button is "running" and despite marking the dose, the button does not press on the substance" of "Genotropin Pen Injectable" was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of a reference sample, an analysis of the complaint history for the involved scope and Annual Product Review. A complaint sample was not returned. The complaint is not confirmed. No root cause or CAPA were identified as the complaint was not confirmed. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability and patient safety. The Issue Escalation (NTM) process determined that no regulatory notification was required. The final scope was determined to be the associated lot of the reported lot A127. The reported defect is not representative of the quality of the batch. Device investigation: The complaint occurred on 22Apr2025, after the expiry date of 31Mar2025; hence, the product was expired during use. There is no evidence that the device constituent part did not perform as expected during its defined shelf-life. As such, this device engineering investigation should be cancelled.

Causality for "was unable to administer the medication.", "the dose adjustment button is "running"" and "despite marking the dose, the button does not press on the substance/device used to administer the hormone to the girl was damaged/device was indeed damage" was determined associated to device constituent of somatropin (malfunction).

Follow-up (22May2025): This is a follow-up report received from a Consumer or other non HCP, Program ID: 164974. Updated information: additional details reported for the event device mechanical issue and clinical course updated.
Follow-up (02Jun2025): This is a follow-up report from the product quality group. Updated information included: investigation results.

Follow-up (06Jun2025): This is a follow-up report from the product quality group.
Updated information: device details.

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 {Lot # nk3089; Exp.Dt. FEB-2027}; Regimen #2	1.0 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # A127}; Regimen #1	; Unknown	Unknown	Unknown; Unknown