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		10 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)

it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose [Device image display issue]
it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose [Device battery issue]
it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose [Product communication issue]

(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) 0.8 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.
PV202500057990

24c. DATE RECEIVED BY MANUFACTURER
10-JUL-2025

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

DATE OF THIS REPORT
15-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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

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.

A 10-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: LK3089, Expiration Date: Feb2027) at 0.8 mg daily and second regimen (Lot number: HF4891, Expiration Date: Jan2026) at 0.8 mg daily, Device Lot Number: L092, Device Expiration Date: 31Jan2026. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE INFORMATION OUTPUT ISSUE (non-serious), DEVICE POWER SOURCE ISSUE (non-serious), PRODUCT COMMUNICATION ISSUE (non-serious) and all described as "it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose".

Additional information: The Genotropin pen was not working, it's not giving him the dose when they put in the dose. it's not resetting to zero. They test it out to see if it was the needle or the cartridge, they change the cartridge but It's the pen that's not giving the dose...it's not setting the dose. As of 13May2025, reporter stated the device did not set the dose of the medication it only show two lines.

Causality for "it's not giving him the dose when they put in the dose. it's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose" was determined associated to device constituent of somatropin (malfunction).
Product Quality Group provided investigational results on 05Jun2025 for somatropin: Investigation Summary and Conclusion: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue, General Display Indicator, was reported. 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.
Product Quality Group provided investigational results on 08Jul2025 for somatropin (device constituent): Site Investigation (Puurs): Battery Died Before Expiry/Display Not Functioning. Injection Device Blocked/Cannot Set Dose/Deliver Dose/Injection Knob/Plunger Does Not/Never Moved. The investigation included reviewing the involved batch records, deviation investigation, evaluation of 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 L092. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution.

Product Quality Group provided investigational summary and conclusion on 10Jul2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: This complaint for "it's not giving him the dose when I put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose...it's the pen that's not giving the dose," for Genotropin Pen was investigated by the manufacturing site. Site Investigation (Puurs): Battery Died Before Expiry/Display Not Functioning The complaint for "it's not marking the dose. it only shows two small lines-one at the top and one at the bottom" of Genotropin Pen Injectable was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of 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 L092. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution. Site Investigation (Puurs): Injection Device Blocked/Cannot Set Dose/Deliver Dose/Injection Knob/Plunger Does Not/Never Moved The complaint for "Does not deliver the dose" 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 L092. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue, General Display Indicator, was reported. 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.

Follow-up (13May2025): This is a spontaneous follow-up report received from a Nurse, Program ID: 164974. Updated information includes drug and device lot number and expiration date, new event of "device battery issue", additional information.

Follow-up (05Jun2025): This is a follow-up report from product quality group.
Updated information: investigation results.
Follow-up (27Jun2025): Follow-up attempts are completed.

Follow-up (08Jul2025): This is a follow-up report from product quality group providing investigation results.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Updated information: product data (drug/device lot number and expiration date) and investigation results (Batch and lot tested and found within specifications).

Follow-up(10Jul2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Investigation results updated.

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 # HF4891; Exp.Dt. JAN-2026}; Regimen #2	0.8 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # L092}; Regimen #1	; Unknown	Unknown	Unknown; Unknown