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	Male	Unk		JUN	2023	

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

the patient was already punctured [Poor quality device used]
the button did not want to go down and did not want to go down [Resistance to movement in device]
already expired [Expired device used]

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

An 11-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 1 mg 1x/day, second regimen

(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 mg, 1x/day	#1) Unknown
#2) 1 mg, 1x/day	#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.
PV202300113327

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

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

DATE OF THIS REPORT
08-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 8

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

(Batch/Lot number: unknown) at 1.2 mg daily (1.2 mg every night) and third regimen (Batch/Lot number: unknown) at 1.5 mg 1x/day, Device Lot Number: W151, Device Expiration Date: 30Apr2024. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE PHYSICAL PROPERTY ISSUE (non-serious) with onset Jun2023, described as "the button did not want to go down and did not want to go down"; POOR QUALITY DEVICE USED (non-serious), described as "the patient was already punctured"; EXPIRED DEVICE USED (non-serious), described as "already expired". The action taken for somatropin and somatropin was unknown.

Causality for "the patient was already punctured", "the button did not want to go down and did not want to go down" and "already expired" was determined associated to device constituent of somatropin (malfunction).

Additional information: The reporter have a question, this week they had a problem with the pen and in the end they were able to solve it. When they went to put the injection, when they have to give it click, that is, when you're going to lower the button, the button did not want to go down and did not want to go down, the patient was already punctured, then what was done was that it was removed, the liquid never came out, they left it still and after a while they tried again and then finally it could be done. The patient had to be punctured twice. Additionally, the reporter indicated that the pen has no expiration date. As on 24Jan2025, reporter stated that her child's device, it's stuck and with the nurse she was waiting for her to report the device, that she will report it and if this defect continues with the device then needs to be change.

Product Quality Group provided investigational results on 07Aug2023 for somatropin (device constituent): The complaint for "The button did not want to lower" 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 reported lot and product type and Annual Product Review. The final scope was determined to be the associated lot of the reported lot W151. A complaint sample was not returned. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability, and patient safety. PGS Puurs concludes that the reported defect is not representative of the quality of the batch and the batch remains acceptable. The NTM process determined that no regulatory notification was required. The reported defect could not be confirmed on the evaluation of the reference sample. No root cause or CAPA were identified as the complaint was not confirmed.

Product Quality Group provided investigational results on 15Sep2024 for somatropin (device constituent): Investigation Summary and Conclusion: The complaint for Genotropin Pen Injectable was investigated. The investigation included reviewing 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 process determined that no regulatory notification was required. The final scope was determined to be the reported product and product type, as no lot was available. Site investigation (Puurs). The complaint occurred on 22May2024, after the expiry date of 30Apr2024; 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.

Product Quality Group provided investigational results on 04Mar2025 for somatropin (device constituent): Investigation Summary and Conclusion: No further investigation is required as no valid lot number or returned sample is available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened.

Product Quality Group provided investigational results on 07Apr2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: The complaint of "The reporter have a question, this week they had a problem with the pen and in the end they were able to solve it. When they went to put the injection, when they have to give it click, that is, when you're going to lower the button, the button did not want to go down and did not want to go down, the patient was already punctured, then what was done was that it was removed, the liquid never came out, they left it still and after a while they tried again and then finally it could be done. The patient had to be punctured twice. Additionally, the reporter indicated that the pen has no expiration date. As on 24Jan2025, reporter stated that her child's device, it's stuck and with the nurse she was waiting for her to report the device, that she will report it and if this defect continues with the device then needs to be change" for Genotropin Pen was investigated by the manufacturing site. Manufacturing Investigation: No further investigation is required as no valid lot number or returned sample is available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened.

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

Follow-up (07Aug2023): This is a follow-up report from product quality group.
Updated information: Device expiration date, investigational results.

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

Follow-up (27Aug2023): Follow-up attempts are completed. No further information is expected.

Follow-up (22May2024): This is a spontaneous report received from contactable reporter (Consumer or other non HCP), Program ID:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

(164974).
Updated information: Reporter tab#1 updated (Alternate Phone added). Reporter tab#3 added. Dosage regimen tab added. New event: Expired device used

Follow-up (15Aug2024): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Follow-up (15Sep2024): This is a follow-up report from product quality group providing investigation results.

Follow-up (24Jan2025): This is a spontaneous follow-up report received from contactable reporter (Consumer or other non HCP), Program ID: (164974).
Updated information: New dosage regimen and gender added, clinical course details added

Follow-up (04Mar2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Event recoded to Resistance to movement in device and investigation results added.

Follow-up (07Apr2025): This is a follow-up report from product quality group providing investigation results. Updated information included: Device 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 #2	1.2 mg every night; Unknown	Unknown	Unknown; Unknown
#1) Genotropin Pen (SOMATROPIN) Solution for injection; Regimen #3	1.5 mg, 1x/day; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # W151}; Regimen #1	1 mg, 1x/day; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # W151; Exp.Dt. APR-2024}; Regimen #2	1.2 mg, every night; Unknown	Unknown	Unknown; Unknown