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		12 Years	Female	Unk		Unk	

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

the girl complains a lot about the needles, they cause her pain when pricked with the needles [Device component defective]
the needles, they cause her pain [Injection site pain]
she cried because the puncture hurt a lot [Crying]

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

A 12-year-old female patient received somatropin (GENOTROPIN PEN), (ongoing) (Lot number: LR7825, Expiration Date: 15Jul2027) at 2.4 mg **(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 # LR7825; Exp.Dt. 15-JUL-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D126}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 2.4 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) Ongoing	#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.
PV202500021715

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

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

DATE OF THIS REPORT
23-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

daily, Device Lot Number: D126, Device Expiration Date: 31Jan2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE ISSUE (non-serious), outcome "unknown", described as "the girl complains a lot about the needles, they cause her pain when pricked with the needles"; INJECTION SITE PAIN (non-serious), outcome "unknown", described as "the needles, they cause her pain"; CRYING (non-serious), outcome "unknown", described as "she cried because the puncture hurt a lot". The action taken for somatropin was unknown.

Causality for "the girl complains a lot about the needles, they cause her pain when pricked with the needles", "the needles, they cause her pain" and "she cried because the puncture hurt a lot" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 24Mar2025 and 22Apr2025 for somatropin (device constituent) for Lot Number: D126: The complaint for 'they cause pain when they prick them with the needles' of 'Genotropin Pen Injectable' was investigated. The investigation included reviewing the involved batch records, deviation investigation, 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 D126. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution.

Additional information: Caregiver indicates: "The girl complains a lot about the needles, they cause her pain when pricked with the needles. Before she didn't complain about the pain and right now she cried because the puncture hurt a lot and it's a needle that shouldn't hurt, the only way the needles hurt is because the entrance edge is flat or the needle is not right." This is repeating itself continuously.

Follow-up (04Mar2025): This is a follow-up report received from a Consumer or other non HCP via product quality group.
Updated information: Expiration Date and Device lot number.

Follow-up (24Mar2025): This is a spontaneous follow-up report received from product quality group.
Updated information included: investigation results.

Follow-up (04Apr2025): Follow-up attempts are completed.

Follow-up (22Apr2025): This is a follow-up report from product quality group.
Updated information included: Device Expiration Date and investigation results for Lot Number: D126 (batch and lot tested and found within specifications).