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		2 Years	Female	Unk	02	JUL	2025	

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

changed the cartridge as if it came out a lot (leakage) [Device leakage]
it looked like lots of bubbles inside [Device physical property issue]

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

A 2-year-old female patient received somatropin (GENOTROPIN PEN), (Lot number: LR7824, Expiration Date: Jun2027) at 0.3 mg 1x/day (0.3 mg, 1x/day (at night)), Device Expiration Date: Jan2027. The patient's relevant medical history and concomitant medications were not reported.

(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 # LR7824; Exp.Dt. JUN-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.3 mg, 1x/day (at night)	#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.
PV202500081152

24c. DATE RECEIVED BY MANUFACTURER
21-AUG-2025

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

DATE OF THIS REPORT
27-AUG-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The following information was reported: DEVICE LEAKAGE (non-serious) with onset 02Jul2025, outcome "unknown", described as "changed the cartridge as if it came out a lot (leakage)"; DEVICE PHYSICAL PROPERTY ISSUE (non-serious) with onset 02Jul2025, outcome "unknown", described as "it looked like lots of bubbles inside".

Causality for "changed the cartridge as if it came out a lot (leakage)" and "it looked like lots of bubbles inside" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational summary and conclusion on 21Aug2025 for somatropin (device constituent): Site investigation (Puurs): Container Leaking During Prep/Use The complaint for "changed the cartridge as if it came out a lot" of 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 (NTM) 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. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. Two distinct Complaint Issues of "Cannot Remove Air" and "Leaking During Loading" were reported. However, these two distinct Complaint Issues map to same Hazard/Hazardous Situation. 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 (INX# 100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Product Quality Group provided investigational summary and conclusion on 22Aug2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: The complaint of The patient's mother says, "My daughter received the medication genotropin and on Wednesday, July 2, I made the change for the first time, that is, after advice, I changed the cartridge as if it came out a lot (leakage) and it stayed on the medication and it looked like lots of blisters inside, and when I tried to remove the air with the pen it didn't come out, so now the medication got blistered, I don't know if it's normal or should do it." Proceed with nurse advisory coordination for Genotopin Pen 5.3 was investigated by the manufacturing site. Site investigation (Puurs): Container Leaking During Prep/Use The complaint for "changed the cartridge as if it came out a lot" of 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 (NTM) 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. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. Two distinct Complaint Issues of "Cannot Remove Air" and "Leaking During Loading" were reported. However, these two distinct Complaint Issues map to same Hazard/Hazardous Situation. 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 (INX# 100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Additional information: The patient's mother stated "My daughter received the medication Genotropin and on Wednesday, 02Jul2025, they changed the cartridge as if it came out a lot (leakage) and it stayed on the medication and it looked like lots of bubbles inside, and when they tried to remove the air with the pen it didn't come out, so now the medication got bubbles. Pen lot number: PAA141175 Follow-up (22Aug2025): Follow-up attempts are completed.

Follow-up(21Aug2025 and 22Aug2025): This is a follow-up report from product quality group providing investigation results. Updated information: Investigation results updated.