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	GUATEMALA		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)

were not instructed on the correct orientation of the ampoule [Health care provider instructions for product use lacking]
they were not instructed on the correct orientation of the ampoule (which should be facing upward)/the cartridge needed to be oriented upward to prevent leaks [Device use error]
significant amount of the product leaked out when she inserted the ampoule into the pen [Device leakage]

Case Description: This is a spontaneous report received from a Consumer or other non HCP 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
#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) 0.8 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.
PV202500063204

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

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

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

DATE OF THIS REPORT
07-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

An 11-year-old female patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 0.8 mg daily. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PRODUCT COMMUNICATION ISSUE (non-serious), described as "were not instructed on the correct orientation of the ampoule"; DEVICE USE ERROR (non-serious), described as "they were not instructed on the correct orientation of the ampoule (which should be facing upward)/the cartridge needed to be oriented upward to prevent leaks"; DEVICE LEAKAGE (non-serious), described as "significant amount of the product leaked out when she inserted the ampoule into the pen". The action taken for somatropin was unknown.

Causality for "were not instructed on the correct orientation of the ampoule", "they were not instructed on the correct orientation of the ampoule (which should be facing upward)/the cartridge needed to be oriented upward to prevent leaks" and "significant amount of the product leaked out when she inserted the ampoule into the pen" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 03Jun2025 for somatropin (device constituent): Site Investigation (Pfizer manufacturing site): No further investigation was required as no valid lot number or returned sample was available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue of "Leaking During Loading" 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 not a current trend alert documented.

Additional Information: The patient's mother stated that a couple of months ago, she had already sent an email with some videos, as she had filed a complaint because a significant amount of the product leaked out when she inserted the ampoule into the pen. She was requesting a replacement for the medication that was lost during the insertion process. Additionally, she mentioned that after the initial training with a nurse on how to use the product, she received a request for information via email, which she completed by submitting a form along with the required evidence. However, during the first two training sessions, they were not instructed on the correct orientation of the ampoule (which should be facing upward). She had recordings of these training sessions, which she had sent by email, showing that this essential step was omitted. As a result, when she installed the cartridge following the initial instructions, the product was lost. It wasn't until a third training session, conducted by a different nurse, that the issue was identified and corrected. They were then informed that the cartridge needed to be oriented upward to prevent leaks. Due to this deficiency in the initial training, two ampoules were wasted. The patient's mother did not want to provide further information because she had already submitted all the necessary data and wanted follow-up on what she had already sent. She insisted that someone from PRIVACY should take responsibility for the lost ampoule. She also mentioned that the form had been submitted back in October of the previous year.

Follow-up (03Jun2025): This is a follow-up report from product quality group providing investigation results.
Follow-up (04Jul2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.