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	COSTA RICA		PRIVACY		Unk	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)

left with half of the dose of Genotropin in his hands [Accidental exposure to product]
left with half of the dose of Genotropin in his hands [Exposure via skin contact]

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

A male patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown).

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ 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)
#1) UNK
#2)

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown
#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)
#1) Unknown
#2) Unknown

19. THERAPY DURATION
#1) 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.
PV202500023181

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

24c. DATE RECEIVED BY MANUFACTURER
16-MAY-2025

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

DATE OF THIS REPORT
16-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: ACCIDENTAL EXPOSURE TO PRODUCT (non-serious), EXPOSURE VIA SKIN CONTACT (non-serious) and all described as "left with half of the dose of Genotropin in his hands". The action taken for somatropin was unknown.

Additional information: Patient's father had already reported that the PEN was failing, they already came to check it, they confirmed that it was failing, that was on 09Feb2025, patient ran out of Genotropin, father just bought one on 23Feb2025, he put it back in and it failed again exactly the same as the previous time and made him waste more or less half of the Genotropin cartridge, he was left with half of the dose of Genotropin in his hands, at the moment of placing the cartridge the whole push device goes up. In charge of an external pharmacy, the situation about the damage of 2 Genotropin devices with a patient, since her father tells her that she has used several boxes of medicine and has not been given an answer. He also comments that they as a pharmacy are going to make the change of the recently purchased device, however, they indicate that the patient's father requests the replacement of the cartridges of the medication.

Product Quality Group provided investigational results on 17Apr2025 for somatropin (device constituent): Investigation Summary and Conclusion: 28Mar2025: Site Investigation: 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, 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 no current trend alert documented. Investigation Summary Complete. Date(GMT): 28Mar2025 Final Approval Date: 17Apr2025 MDCP Investigation Summary and Conclusion: This complaint for..."Patient's father had already reported that the PEN was failing, they already came to check it, they confirmed that it was failing, that was on 09Feb2025, patient ran out of Genotropin, father just bought one on 23Feb2025, he put it back in and it failed again exactly the same as the previous time and made him waste more or less half of the Genotropin cartridge,...he was left with half of the dose of Genotropin in his hands, at the moment of placing the cartridge the whole push device goes up"...for GENOTROPIN PEN.

Follow-up (17Apr2025): This is a follow-up report from product quality group providing investigation results
Follow-up (16May2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.