CIOMS FORM

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		13 Years	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)

she does not know if she is placing the medication correctly or if it is the device that is failing / doubts when placing the vials and we are wasting medicine [Health care provider instructions for product use lacking]
waste medicine [Device leakage]
we no longer had the problem and we were able to continue applying the medication without inconvenience [Poor quality device used]

Case Description: This is a spontaneous report received from a Consumer or other non HCP and a Physician 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 **(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) 1.6 mg, 1x/day	#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.
PV202400161372

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

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

DATE OF THIS REPORT
29-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 5

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

A 13-year-old male patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 1.6 mg 1x/day and second regimen (Batch/Lot number: unknown) at 0.1 mg 1x/day. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PRODUCT COMMUNICATION ISSUE (non-serious), described as "she does not know if she is placing the medication correctly or if it is the device that is failing / doubts when placing the vials and we are wasting medicine"; DEVICE LEAKAGE (non-serious), described as "waste medicine"; POOR QUALITY DEVICE USED (non-serious), described as "we no longer had the problem and we were able to continue applying the medication without inconvenience". The action taken for somatropin was unknown.

Causality for "she does not know if she is placing the medication correctly or if it is the device that is failing / doubts when placing the vials and we are wasting medicine", "waste medicine" and "we no longer had the problem and we were able to continue applying the medication without inconvenience" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 30Dec2024, 22Jan2025 and 12Feb2025 for somatropin (device constituent): Investigation Summary and Conclusion: Site Investigation (Pfizer 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 "IFU - Unclear" was reported. An additional Complaint Issue of "Leaking During Prep/Use" was reported. This Complaint Issue is considered a cascading event of "IFU - Unclear". 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. MDCP Investigation Summary and Conclusion: This complaint for GENOTROPIN PEN 12 of (Patient's caretaker says: I would like face-to-face counseling, since we are having doubts when it comes to placing the vials and we are wasting medication, both of us doctors, but we don't know the reason why we both waste medication.), was received.

Additional information: she does not know if she is placing the medication correctly or if it is the device that is failing. Patient caregiver indicated: I would like face-to-face consultancy, since we are having doubts when placing the vials and we are wasting medicine, we doctors both, but we do not know the reason why we both waste medicine. As of 23Apr2025 it has been reported that the patient's mom indicated that her son was using Genotropin since around Nov2024. At some point during the application, the pen they were given started to present certain difficulties. She spoke with the nurse assigned to them and explained what was happening. Fortunately, they didn't have the problem anymore and were able to continue administering the medication without issues. Some time later, approximately at the end of the second month, it happened that there was no availability of Genotropin in Guatemala. Since they couldn't acquire it locally, they bought it in Mexico. The presentation that came there already had the pens loaded, so they didn't need to use the pen they were initially given. Since there was no Genotropin in Guatemala, they bought it for two consecutive months in Mexico. When they were informed that it had been brought back to Guatemala, they bought it again locally. The problem was that they started having the same difficulty with the pen again. That was why patient's mom was calling, because she needed that pen changed, as it was defective. In fact, the device presented problems from the first weeks of use. At that time, she didn't want to change it because it started working again, and then they didn't use it for a while as they were using the product we bought in Mexico. Now they had a new batch of Genotropin, bought here, and she needed the device changed.

Follow-up (15Jan2025): This is a follow-up report from product quality group providing a device code.

Follow-up (22Jan2025): This is a follow-up report from product quality group providing investigation results.

Follow-up (12Feb2025): This is a follow-up report from product quality group providing investigation results.
Updated information included: Investigation conclusion added.

Follow-up (26Feb2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Follow-up (23Apr2025): This is a spontaneous report received from a Consumer or other non HCP and a Physician from product quality group, Program ID: 164974.
Updated information: New event added (Poor quality device used)

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	0.1 mg, 1x/day; Unknown	Unknown	Unknown; Unknown

Mfr. Control Number: PV202400161372

ADDITIONAL 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
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection; Regimen #1	; Unknown	Unknown	Unknown; Unknown