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		11 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 one the patient had was damaged, the device was broken [Device defective]
the one the patient had was damaged, the device was broken [Device breakage]

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

An 11-year-old female patient (unknown if pregnant) received somatropin

(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) 1.3 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.
PV202400054027

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

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

DATE OF THIS REPORT
09-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

(GENOTROPIN PEN), (ongoing) (Batch/Lot number: unknown) at 1.3 mg daily. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE DEFECTIVE (non-serious), DEVICE BREAKAGE (non-serious), outcome "unknown" and all described as "the one the patient had was damaged, the device was broken". The action taken for somatropin was unknown.

Causality for "the one the patient had was damaged, the device was broken" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 05Sep2024 for somatropin (device constituent): The complaint for "I have trouble placing the genotropin medication" of "Genotropin Pen" 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: The only information reported in this complaint is "I'm having trouble applying the GENOTROPIN medication, I cannot use the device". There is insufficient information to investigate this complaint. Thus, no additional investigation is necessary. This device engineering investigation should be cancelled.

Product Quality Group provided investigational results on 04Mar2025 for somatropin (device constituent): Investigation Summary and Conclusion: 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, Loss of Function, 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.

Product Quality Group provided investigational results on 08Apr2025 for somatropin (device constituent): MDCP Investigation Summary and Conclusion: The complaint of the reporter called to request another pen for Genotropin 5.3 mg because the one the patient had was damaged, the device was broken, the reporter no longer had the device, the reporter threw it away for Genotropin Pen was received.

Additional information: the reporter called to request another pen for Genotropin 5.3 mg because the one the patient had was damaged, the device was broken, the reporter no longer had the device, the reporter threw it away

Batch/lot number is not provided, and it cannot be obtained.

Follow-up (05Sep2024): This is a follow-up report from the product quality group. Updated information: investigation results.
Follow-up (10Sep2024): This is a follow-up report from the product quality group. Updated information: investigation results.
Follow-up (04Feb2025): This is a spontaneous follow-up report received from a consumer, Program ID: 164974. Updated information: Product details (dose, units, frequency and dose description). New event ("the one the patient had was damaged, the device was broken"). Clinical course.
Amendment: This follow-up report is being submitted to amend previous information: to add a device code.
Follow-up (04Mar2025): This is a follow-up report from the product quality group. Updated information: investigation results.
Follow-up (20Mar2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.
Follow-up (08Apr2025): This is a follow-up report from the product quality group. Updated information included: investigation results, event removed (Device difficult to use) and event coded (Device defective).