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	GUATEMALA		PRIVACY		1 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)

device did not work/the device is damaged [Device defective]

Case Description: The initial case was missing the following minimum criteria: Adverse event.

(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 **(Continued on Additional Information Page)**

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

15. DAILY DOSE(S)
#1) 0.2 mg, daily
#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.
PV202500066052

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

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

DATE OF THIS REPORT
18-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

Mfr. Control Number: PV202500066052

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Upon receipt of follow up information on 29May2025, this case now contains all required information to be considered valid.

This is a spontaneous report received from a Physician and a Nurse from product quality group, Program ID: 164974.

An 1-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 0.2 mg daily and second regimen (Batch/Lot number: unknown) at 0.5 mg daily, Device Lot Number: 0126. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE DEFECTIVE (non-serious), outcome "unknown", described as "device did not work/the device is damaged".

Causality for "device did not work/the device is damaged" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 13Jun2024 for somatropin (device constituent): Investigation Summary and Conclusion: 13-JUNE-2025/CLAU. 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. Two distinct Complaint Issues of "Cartridge/Syringe Barrel Broken During Prep/Use" and "Loss of Function" 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 lives in the United States and syringes have been damaged, appointment with the nurse scheduled because the device did not work, doctor states that he did not order the medication because the device is damaged, the nurse indicated that there was a quality complaint because the pen was in poor condition.

Follow-up (13Jun2025): This is a follow-up report from product quality group providing investigation results.
Updated information: QC results added

The information on the batch/lot number for somatropin will be requested and submitted if and when received.
Follow-up (18Jul2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

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	0.5 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # 0126}; Regimen #1	; Unknown	Unknown	Unknown; Unknown