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		7 Years	Male	Unk	02	JUN	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

It caused him pain and discomfort [Injection site pain]
It caused him pain and discomfort [Injection site discomfort]
The pen was damaged, the plastic part that goes on top was damaged [Device breakage]

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

A 7-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: lr7825, Expiration Date: May2027) at 0.6 mg 1x/day, Device

(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 {Lot # lr7825; Exp.Dt. MAY-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # lb7549}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.6 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.
PV202500067101

24c. DATE RECEIVED BY MANUFACTURER
11-JUN-2025

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

DATE OF THIS REPORT
13-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Lot Number: lb7549, Device Expiration Date: Mar2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: INJECTION SITE PAIN (non-serious), INJECTION SITE DISCOMFORT (non-serious) all with onset 02Jun2025, outcome "unknown" and all described as "It caused him pain and discomfort"; DEVICE BREAKAGE (non-serious), outcome "unknown", described as "The pen was damaged, the plastic part that goes on top was damaged". The action taken for somatropin was unknown.

Causality for "it caused him pain and discomfort" and "the pen was damaged, the plastic part that goes on top was damaged" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational results on 11Jun2025 for somatropin (device constituent): Investigation Summary and Conclusion: 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, Component Damaged During Prep/Use, was reported. There is no indication that the complaint of "it did cause patient pain and discomfort" is related to the malfunction or misuse of a device constituent part. This is related to injection site pain, which is out of scope of device engineering. 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.

Additional Information: The patient manager indicated: "My son is undergoing GENOTROPIN treatment, but the pen was damaged, the plastic part that goes on top was damaged. It urges me because yesterday (02Jun2025) we did the process and it did cause him pain and discomfort." He also indicated: "Here in the country they do not sell the pen, I call everywhere and they do not sell it."

Follow-up (11Jun2025): This is a follow-up report from the product quality group. Updated information included: investigation results.