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		8 Years	Female	Unk			2025	

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

vomited twice [Vomited]
nausea [Nausea]
the needle was hurting [Injection site pain]
pen was getting stuck in the part of the syringe [Resistance to movement in device]

Case Description: This is a spontaneous report received from a Consumer or other non HCP and a Nurse 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 {Lot # LR7825; Exp.Dt. 15-MAY-2027}
#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) 0.8 mg, daily (night time)	#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) 2025 / 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.
PV202500026807

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

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

DATE OF THIS REPORT
24-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 4

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

An 8-year-old female patient received somatropin (GENOTROPIN PEN), since 2025 (Lot number: LR7825, Expiration Date: 15May2027) at 0.8 mg daily (0.8 mg, daily (night time)). The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE PHYSICAL PROPERTY ISSUE (non-serious) with onset 2025, outcome "unknown", described as "pen was getting stuck in the part of the syringe"; INJECTION SITE PAIN (non-serious) with onset 2025, outcome "unknown", described as "the needle was hurting"; VOMITING (non-serious), outcome "unknown", described as "vomited twice"; NAUSEA (non-serious), outcome "unknown". The action taken for somatropin was unknown.

Causality for "the needle was hurting" and "pen was getting stuck in the part of the syringe" was determined associated to device constituent of somatropin (malfunction).
Product Quality Group provided investigational results on 07Jul2025 for somatropin (device constituent): 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. An additional Complaint Issue of Injection Failure/Blocked was reported. This Complaint Issue is considered a cascading event. 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# INX100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Additional information: As of 17Jun2025, caregiver reported that the pen was getting stuck in the part of the syringe, when she pricked it got stuck and the needle was hurting, it had only been 3 months with the pen. As of 19Jun2025, a reporter indicated that upon checking it, it was confirmed that the needle holder had a spring which had lost its strength and no longer applied pressure to the button. It was possible to put it already out of the refrigeration and out of the refrigeration it worked very well.

Follow-up (13Apr2025): Follow-up attempts are completed.

Follow-up (17Jun2025). This is a spontaneous follow-up report received from a consumer. Updated information included: dose description, new events "pen was getting stuck in the part of the syringe" and "the needle was hurting" were added; clinical course updated.

Follow-up (19Jun2025): This is a Spontaneous follow-up report received from Nurse, Program ID: 164974. Updated information: Reporter information and additional information updated.

Follow-up (07Jul2025): This is a follow-up report from product quality group providing investigation results.
Follow-up (21Jul2025): This is a follow-up report from product quality group providing investigation results. Updated information included: expiration date.