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		8 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)

when I had to load the new dose, I had that inconvenience and it no longer allows me to dose in the device [Health care provider instructions for product use lacking]
lost more than half of the medication [Device leakage]
made the decision not to administer the medication to the patient for the time being [Drug dose omission by device]

Case Description: This is a spontaneous report received from a Consumer or other non HCP and a Nurse, 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. MAY-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D126}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.6 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) 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.
PV202500056642

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

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

DATE OF THIS REPORT
14-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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), (Lot number: LR7825, Expiration Date: May2027) at 1.6 mg daily, Device Lot Number: D126. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PRODUCT COMMUNICATION ISSUE (non-serious), described as "when I had to load the new dose, I had that inconvenience and it no longer allows me to dose in the device"; DEVICE LEAKAGE (non-serious), described as "lost more than half of the medication"; DRUG DOSE OMISSION BY DEVICE (non-serious), described as "made the decision not to administer the medication to the patient for the time being". The action taken for somatropin was unknown.

Causality for "when i had to load the new dose, i had that inconvenience and it no longer allows me to dose in the device", "lost more than half of the medication" and "made the decision not to administer the medication to the patient for the time being" was determined associated to device constituent of somatropin (malfunction).

Additional Information: The patient manager indicated: "My GENOTROPIN device, saw that it no longer allows me to mark there the units that I need to administer to my daughter and saw that yesterday (07May2025) that I was going to change it, I lost more than half of the medication because when I wanted to see, it shot up by itself and the medication came out. So, I want to see if someone can support me or how I can acquire a new device, I make the space, I interrupt my activities there in order to solve that, because yes, as I say, yesterday when I had to load the new dose, I had that inconvenience and it no longer allows me to dose in the device the dose that I have to administer to my daughter." On 09May2025, the nurse indicated: "There was a quality complaint from the person in charge, when he made the replacement of the cartridge of GENOTROPIN 12mg, when they wanted to put the ideal dose which is 0.6mg, they could only put 0.2mg, and the cartridge spilled completely, leaving a minimal part in the cartridge." The person in charge made the decision not to administer the medication to the patient for the time being, until it was verified that it works properly. Took into account that the counseling with the patient's caregiver was virtual, however, the nurse recommended that face-to-face counseling should be coordinated to verify the pen. At the time of making the satisfaction survey call, the patient's mother did not report any report and did not refer that she needs other advice.