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		3 Years	Female	Unk	14	MAY	2025

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

it's been three days with no medication coming out. [Drug dose omission by device]
the medication did not come out of the needle [Device blockage]
that the plunger of the pen did not return to the top, that is why a certain part of the cartridge spilled, that is, She did not make the replacement correctly [Device handling error]

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)

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 # LN4285; Exp.Dt. FEB-2027}
#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)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.6 mg, daily (at night)	#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.
PV202500058000

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

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

DATE OF THIS REPORT
25-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 2

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

NAME AND ADDRESS WITHHELD.

Mfr. Control Number: PV202500058000

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 3-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Lot number: LN4285, Expiration Date: Feb2027) at 0.6 mg daily (0.6 mg, daily (at night)) and second regimen (Lot number: LD7549, Expiration Date: Mar2027) at 0.6 mg daily (0.6 mg, daily (at night)), Device Lot Number: D154, Device Expiration Date: Mar2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE USE ERROR (non-serious) with onset 14May2025, described as "that the plunger of the pen did not return to the top, that is why a certain part of the cartridge spilled, that is, She did not make the replacement correctly"; DRUG DOSE OMISSION BY DEVICE (non-serious), described as "it's been three days with no medication coming out."; DEVICE OCCLUSION (non-serious), described as "the medication did not come out of the needle". The action taken for somatropin was unknown.

Causality for "it's been three days with no medication coming out.", "the medication did not come out of the needle" and "that the plunger of the pen did not return to the top, that is why a certain part of the cartridge spilled, that is, she did not make the replacement correctly" was determined associated to device constituent of somatropin (malfunction).

Additional information: On 15May2025: Nurse indicates: "In face-to-face counseling with this patient who went at two in the afternoon of May 14, the person in charge reports that she made a cartridge change and a certain part of the cartridge spilled in the refill. But it is observed that the plunger of the pen did not return to the top, that is why a certain part of the cartridge spilled, that is, She did not make the replacement correctly. She forgot the step of returning the plunger of the pen until it reached the top counterclockwise, it is important considering that the person in charge had already made three previous replacements, so she is given advice again from the beginning and the revision of the pen is carried out with a placebo again, The placebo and PEN is in perfect condition for use. It is worth mentioning that the person in charge of poor communication from the Social Security here in Guatemala never communicated with the Pfizer Me Cuida call center for the scheduling of the advice, that is, she did it on her own, yesterday she already received advice and obviously she did tell me that she was doing the procedure wrong." As of 20Jun2025, a reporter indicated that The person in charge said that she made a cartridge replacement and a certain part of the cartridge spilled since in the replacement the pen plunger did not return to the top counterclockwise, Pen Lot Number D154 Case Lot Number LD7549. Expiration Date Mar2027. Taking into account that he had already made three cartridge replacements. So advice is given on how to make the replacement correctly, and when checking the Pen it is in perfect condition for use. It is worth mentioning that due to poor communication from the Social Security he had not received the corresponding advice for the use of Genotropin 12mg.

Follow-up (15May2025): This is a spontaneous follow-up report received from a Nurse, Program ID: 164974. Updated information includes: new dosage regimen, new event (Device use error) and clinical course details.

Follow-up (20Jun2025): This is a Spontaneous follow-up report received from Nurse, Program ID: 164974
Updated information: Additional information updated.

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 {Lot # LD7549; Exp.Dt. MAR-2027}; Regimen #2	0.6 mg, daily (at night); Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # D154}; Regimen #1	; Unknown	Unknown	Unknown; Unknown