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	DOMINICAN REPUBLIC		PRIVACY		13 Years	Male	Unk		Unk		

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

need another training [Product communication issue]
when I was trying to get the air out, all the fluid went out [Device leakage]
she did it incorrectly, and the entire contents of the ampoule were wasted / made a misplacement of the medication and all the medication in the vial was wasted [Wrong technique in device usage process]

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 # LR7824; Exp.Dt. JUN-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # LD7551}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.8 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.
PV202500076289

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

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

DATE OF THIS REPORT
01-JUL-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

A 13-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: LR7824, Expiration Date: Jun2027) at 1.8 mg daily, Device Lot Number: LD7551, Device Expiration Date: Jan2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PRODUCT COMMUNICATION ISSUE (non-serious), outcome "unknown", described as "need another training"; DEVICE LEAKAGE (non-serious), outcome "unknown", described as "when I was trying to get the air out, all the fluid went out"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), outcome "unknown", described as "she did it incorrectly, and the entire contents of the ampoule were wasted / made a misplacement of the medication and all the medication in the vial was wasted". The action taken for somatropin was unknown.

Causality for "need another training", "when i was trying to get the air out, all the fluid went out" and "she did it incorrectly, and the entire contents of the ampoule were wasted / made a misplacement of the medication and all the medication in the vial was wasted" was determined associated to device constituent of somatropin (malfunction).

Additional information: Patient reported 'I want to report that last night, I was trying to prepare a blister and the blister when I was trying to get the air out, all the fluid went out. I need another training, please, because I have no way to medicate the child today, because my problem is when I'm taking the air out of the injection, the blister seems like I don't know, I don't know it. I put it on, she told me to kind of put it in 00 or in a row, and I did it incorrectly, and the entire contents of the ampoule were wasted, since I lost a dose, a complete blister.'
As for 24Jun2025 Patient reported 'I reported the blister, but it turns out that I don't have a way to put it on today. When the nurse came, she made me one and I saw everything and I understood everything, but last night, when I ran out of dose, which I had to prepare another, all the liquid was thrown out and now I don't know how to prepare it and I don't want to leave the child unmedicated today, today I'm not going to put it because I'm afraid that another blister is going to break.'
As for 26Jun2025 Nurse indicated: 'The mother tells me that when she went to place the medication, she made a misplacement of the medication and all the medication in the vial was wasted'.