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		12 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)

Dose: 12.5 mg daily [Drug dose prescribing error]
we give the injection, we cannot press the liquid so it does not come out of the device [Mechanical device firing issue]
we give the injection, we cannot press the liquid so it does not come out of the device [Device mechanical issue]

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

A 12-year-old male patient received somatropin (GENOTROPIN PEN), **(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 # LR78256; Exp.Dt. MAY-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # LD7549}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 12.5 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) MAR-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.
PV202500097032

24c. DATE RECEIVED BY MANUFACTURER
07-AUG-2025

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

DATE OF THIS REPORT
13-AUG-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

since Mar2025 (Lot number: LR78256, Expiration Date: May2027) at 12.5 mg 1x/day, Device Lot Number: LD7549, Device Expiration Date: Mar2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: PRODUCT PRESCRIBING ERROR (non-serious), described as "Dose: 12.5 mg daily"; DEVICE MALFUNCTION (non-serious), DEVICE MECHANICAL ISSUE (non-serious) and all described as "we give the injection, we cannot press the liquid so it does not come out of the device". The action taken for somatropin was unknown.

Causality for "we give the injection, we cannot press the liquid so it does not come out of the device" was determined associated to device constituent of somatropin (malfunction).

Additional Information: The patient manager indicated: "We have already administered three doses of GENOTROPIN to the child (patient), in the months of March, April and May, but in June the dose could not be applied because the insurance had not authorized it, it already authorized it but we have a problem with the device (pen), because when we give the injection, we cannot press the liquid so it does not come out of the device."