CIOMS FORM

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	COSTA RICA		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)

2 days of not injecting him/and it's been four days without my son being able to receive the hormone [Drug dose omission by device]
it is damaged [Device defective]
caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work [Wrong technique in device usage process]
caregiver wasted a dose of medication trying to figure out how to fix it [Device leakage]

Case Description: This is a spontaneous report received from a Consumer or other non HCP, 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 # KC8721; Exp.Dt. JAN-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) 1.4 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.
PV202500052615

24c. DATE RECEIVED BY MANUFACTURER
29-APR-2025

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

DATE OF THIS REPORT
07-MAY-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

A 13-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: KC8721, Expiration Date: Jan2027) at 1.4 mg daily. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DRUG DOSE OMISSION BY DEVICE (non-serious), outcome "unknown", described as "2 days of not injecting him/and it's been four days without my son being able to receive the hormone"; DEVICE DEFECTIVE (non-serious), outcome "unknown", described as "it is damaged"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), outcome "unknown", described as "caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work"; DEVICE LEAKAGE (non-serious), outcome "unknown", described as "caregiver wasted a dose of medication trying to figure out how to fix it ". The action taken for somatropin was temporarily withdrawn.

Causality for "2 days of not injecting him/and it's been four days without my son being able to receive the hormone", "it is damaged", "caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work" and "caregiver wasted a dose of medication trying to figure out how to fix it " was determined associated to device constituent of somatropin (malfunction).

Additional information: The patient's caregiver stated his son's pen got damaged, that they would send someone and replace the pen. Additionally, caregiver wasted a dose of medication trying to figure out how to fix it and it doesn't work. It's been 2 days since she last injected him. The patient's mother reported that the pen got damaged, it shows an error and the error won't go away. She stated it's been four days without my son being able to receive the hormone, and she urgently need to resolve this