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	DOMINICAN REPUBLIC		PRIVACY		10 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)

it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose [Device image display issue]
it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose [Device battery issue]
it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose [Product communication issue]

(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 # LK3089; Exp.Dt. FEB-2027}
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # HF4891}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.8 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.
PV202500057990

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

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

DATE OF THIS REPORT
10-JUN-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

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

A 10-year-old male patient received somatropin (GENOTROPIN PEN), (Lot number: LK3089, Expiration Date: Feb2027) at 0.8 mg daily, Device Lot Number: HF4891, Device Expiration Date: Jan2026. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE INFORMATION OUTPUT ISSUE (non-serious), DEVICE POWER SOURCE ISSUE (non-serious), PRODUCT COMMUNICATION ISSUE (non-serious), outcome "unknown" and all described as "it's not giving him the dose when they put in the dose. It's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose".

Causality for "it's not giving him the dose when they put in the dose. it's not resetting to zero. it's the pen that's not giving the dose...it's not setting the dose" was determined associated to device constituent of somatropin (malfunction).

Additional information: The Genotropin pen was not working, it's not giving him the dose when they put in the dose. it's not resetting to zero. They test it out to see if it was the needle or the cartridge, they change the cartridge but It's the pen that's not giving the dose...it's not setting the dose. As of 13May2025, reporter stated the device did not set the dose of the medication it only show two lines.

Product Quality Group provided investigational results on 05Jun2025 for somatropin: Investigation Summary and Conclusion: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue, General Display Indicator, was reported. The Risk Management File was reviewed to confirm that the Hazard(s) and Hazardous Situation(s) associated with the Complaint Issue are documented in the Hazard Analysis (INX100281795), Version (9.0). All complaint investigations are trended. There is no current trend alert documented.

Follow-up (13May2025): This is a spontaneous follow-up report received from a Nurse, Program ID: 164974. Updated information includes drug and device lot number and expiration date, new event of "device battery issue", additional information.

Follow-up (05Jun2025): This is a follow-up report from product quality group.
Updated information: investigation results.