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	Female	Unk		Unk		

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

the cartridge broke it was that it sounded like an explosion [Device breakage]
when the mother placed the ampoule she completely threw away the medication, indicating that it was a mismanagement by the patient's mother [Wrong technique in device usage process]

Case Description: The initial case was missing the following minimum criteria: Adverse event. Upon receipt of follow up information on 25Feb2025, this case now contains all required information to be considered valid.

(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
#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) 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.
PV202500024487

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

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

DATE OF THIS REPORT
17-APR-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

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

A 10-year-old female patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown). The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE BREAKAGE (non-serious), described as "the cartridge broke it was that it sounded like an explosion"; WRONG TECHNIQUE IN DEVICE USAGE PROCESS (non-serious), described as "when the mother placed the ampoule she completely threw away the medication, indicating that it was a mismanagement by the patient's mother". The action taken for somatropin was unknown.

Causality for "the cartridge broke it was that it sounded like an explosion" and "when the mother placed the ampoule she completely threw away the medication, indicating that it was a mismanagement by the patient's mother" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational summary and conclusion on 07Apr2025 for somatropin (device constituent): Site Investigation (Puurs): No further investigation was required as no valid lot number or returned sample was available. This complaint will continue to be trended. If additional information becomes available, this complaint will be reopened. Device Investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. The Complaint Issue "Cartridge Glass Broken/Cracked During Loading/Unloading" 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 (INX# 100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Follow-up(07Apr2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Investigation results added.
Follow-up (17Apr2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.