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	PANAMA		PRIVACY		6 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)

painful injection [Injection site pain]
the medication could not be administered [Drug dose omission by device]
injection process was difficult because the pen was not friendly/it is difficult for me to use it [Device difficult to use]
the needles of the pen were damaged [Needle issue]
the pen turned with difficulty/dosing button was jammed, it did not turned/it doesn't screw it on properly [Device mechanical jam]
80% of the medication was spilled. [Device leakage]
the numbers were not visible [Device image display 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
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution **(Continued on Additional Information Page)**

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.
PV202500046317

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

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

DATE OF THIS REPORT
13-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 3

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 from product quality group, Program ID: 164974.

A 6-year-old female patient received somatropin (GENOTROPIN PEN), first regimen (Batch/Lot number: unknown) at 0.8 mg daily and second regimen (Batch/Lot number: unknown) at 0.6 mg daily, Device Lot Number: A143, Device Expiration Date: 31May2025. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: INJECTION SITE PAIN (non-serious), outcome "unknown", described as "painful injection"; DRUG DOSE OMISSION BY DEVICE (non-serious), outcome "unknown", described as "the medication could not be administered"; DEVICE DIFFICULT TO USE (non-serious), outcome "unknown", described as "injection process was difficult because the pen was not friendly/it is difficult for me to use it"; NEEDLE ISSUE (non-serious), outcome "unknown", described as "the needles of the pen were damaged"; DEVICE MECHANICAL ISSUE (non-serious), outcome "unknown", described as "the pen turned with difficulty/dosing button was jammed, it did not turned/it doesn't screw it on properly"; DEVICE LEAKAGE (non-serious), outcome "unknown", described as "80% of the medication was spilled."; DEVICE INFORMATION OUTPUT ISSUE (non-serious), outcome "unknown", described as "the numbers were not visible". The action taken for somatropin was unknown.

Causality for "painful injection", "the medication could not be administered", "injection process was difficult because the pen was not friendly/it is difficult for me to use it", "the needles of the pen were damaged", "the pen turned with difficulty/dosing button was jammed, it did not turned/it doesn't screw it on properly", "80% of the medication was spilled." and "the numbers were not visible" was determined associated to device constituent of somatropin (malfunction).

Product Quality Group provided investigational summary and conclusion on 10Jun2025 for somatropin (device constituent): Site investigation (Puurs): The complaint for "the dosing knob, was blocked and did not rotate." of "Genotropin Pen Injectable" was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of reference sample, an analysis of the complaint history for the involved scope and Annual Product Review. A complaint sample was not returned. The complaint is not confirmed. No root cause or CAPA were identified as the complaint was not confirmed. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability and patient safety. The Issue Escalation (NTM) process determined that no regulatory notification was required. The final scope was determined to be the associated lot of the reported lot "A143". The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution. Site investigation (Puurs): The complaint for "it leaked like 80% of the medication" of Genotropin Pen Injectable was investigated. The investigation included reviewing the involved batch records, deviation investigation, evaluation of reference sample, an analysis of the complaint history for the involved scope and Annual Product Review. A complaint sample was not returned. The complaint is not confirmed. No root cause or CAPA were identified as the complaint was not confirmed. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability and patient safety. The Issue Escalation (NTM) process determined that no regulatory notification was required. The final scope was determined to be the associated lot of the reported lot A143. The reported defect is not representative of the quality of the batch. Device engineering investigation: This investigation is based on the information captured in the Complaint Description and Argus Report. Three distinct Complaint Issues of Injection Knob/Dial Issue, Needle Bent/Broken and Leaking During Prep/Use were reported. However, these three distinct Complaint Issues map to the same Hazard/Hazardous Situation. The issue of needle damaged is interpreted as needle broken. The issue with Purple pen has been investigated in DEI INV- 351548 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# INX100281795, Version # (9.0)). All complaint investigations are trended. There is no current trend alert documented.

Additional information: Reporter stated the needles of the pen were damaged and the medication could not be administered because the pen turned with difficulty and the numbers were not visible, so it was not possible to set the dose. Reporter mentioned that she had two daughters and the injection process was difficult because the pen was not friendly and this led to a painful injection and she did not know if it was because of the pen or a bad administration technique. Reporter also stated that she set the medication and it did not screw correctly so 80% of the medication was spilled. Nurse stated the dosing button was jammed, it did not turned. On 16Apr2025, patient's mother reported that The pen is damaged, it is difficult for her to use it. On 30Apr2025, the reporter stated that during the consultation, the pen was checked and it was observed that the dosing knob was stuck, it did not turn.

Follow-up (16Apr2025): This is a spontaneous follow-up report received from a Consumer or other non-HCP, Program ID: 164974. Updated information included: Reaction data (event Device difficult to use subsumed, verbatim updated); clinical course

Follow-up (30Apr2025): This is a spontaneous follow-up report received from a Nurse. Updated information included: Product information (dosage, expiration date), Clinical course details added.
Batch/lot number is not provided, and it cannot be obtained.
Follow-up (29May2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

Follow-up(10Jun2025): This is a follow-up report from product quality group providing investigation results.
Updated information: Investigation results updated.

Mfr. Control Number: PV202500046317

ADDITIONAL INFORMATION

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Genotropin Pen (SOMATROPIN) Solution for injection; Regimen #2	0.6 mg, daily; Unknown	Unknown	Unknown; Unknown
#2) Genotropin Pen (SOMATROPIN (DEVICE CONSTITUENT)) Solution for injection {Lot # A143}; Regimen #1	; Unknown	Unknown	Unknown; Unknown