

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY COSTA RICA	2. DATE OF BIRTH			2a. AGE 4 Years	3. SEX Female	3a. WEIGHT Unk	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION ☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING
		Day	Month	Year				Day	Month	Year	
			PRIVACY					Unk			

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
Pen is expired and is having issues [Device defective]

Case Description: The initial case was missing the following minimum criteria: Adverse event.

(Continued on Additional Information Page)

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 {Lot # W151}		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA
15. DAILY DOSE(S) #1) 0.7 mg, daily #2)	16. ROUTE(S) OF ADMINISTRATION #1) Unknown #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) #1) Unknown #2) Unknown	19. THERAPY DURATION #1) 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. PV202500054735	
24c. DATE RECEIVED BY MANUFACTURER 04-JUN-2025	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☒ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous	
DATE OF THIS REPORT 09-JUN-2025	25a. REPORT TYPE ☐ INITIAL ☒ FOLLOWUP: 2	

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

NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

09-Jun-2025 16:57

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

Upon receipt of follow up information on 07May2025, this case now contains all required information to be considered valid.

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

A 4-year-old female patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 0.7 mg daily, Device Lot Number: W151, Device Expiration Date: Apr2024. The patient's relevant medical history and concomitant medications were not reported.

The following information was reported: DEVICE DEFECTIVE (non-serious), described as "Pen is expired and is having issues".

Causality for "pen is expired and is having issues" was determined associated to device constituent of somatropin (malfunction).

Additional Information: Pen is expired and is having issues. Through the lot of the box (FH2003), it was possible to verify that the pen belongs to lot W151. As of 04Jun2025, reporter stated the pen is expired since last year but the hospital won't change it until it stops working.

Follow-up (14May2025): This is a spontaneous report received from a Nurse and a Consumer or other non HCP from product quality group.

Updated information: device lot number, expired device used deleted.

Follow-up (04Jun2025): This is a spontaneous follow-up report received from a Consumer or other non-HCP, Program ID: (164974).

Updated information includes: additional information.