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		3 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 device was apparently exposed to moisture, as she sent it with another person to a beach resort, and it seems the device got wet/ it was transported in a cooler with ice and got wet [Device moisture damage]
sometimes it shoots out all at once and the medicine comes out [Device leakage]
The screen became dislocated and is not displaying the numbers correctly [Device image display issue]
the device was apparently exposed to moisture, as she sent it with another person to a beach resort, and it seems the device got wet. [Device handling error]

(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 {Lot # D129}

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 0.5 mg, 1x/day	#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.
PV202500102787

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

24c. DATE RECEIVED BY MANUFACTURER
22-AUG-2025

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

DATE OF THIS REPORT
02-SEP-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: This is a spontaneous report received from a Nurse from product quality group, Program ID: 164974.

A 3-year-old female patient received somatropin (GENOTROPIN PEN), (Batch/Lot number: unknown) at 0.5 mg 1x/day, Device Lot Number: D129, Device Expiration Date: 31Jan2027. The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE PHYSICAL PROPERTY ISSUE (non-serious), described as "the device was apparently exposed to moisture, as she sent it with another person to a beach resort, and it seems the device got wet/ it was transported in a cooler with ice and got wet"; DEVICE LEAKAGE (non-serious), described as "sometimes it shoots out all at once and the medicine comes out"; DEVICE INFORMATION OUTPUT ISSUE (non-serious), described as "The screen became dislocated and is not displaying the numbers correctly"; DEVICE USE ERROR (non-serious), described as "the device was apparently exposed to moisture, as she sent it with another person to a beach resort, and it seems the device got wet.". The action taken for somatropin was unknown.

Additional information: Nurse indicated: "The patient's mother with the appointment scheduled for today (22Aug2025) at 10 am does not have the genotropin device on hand. She told me the device is malfunctioning, but she couldn't show me exactly what is happening. She explained that the device was apparently exposed to moisture, as she sent it with another person to a beach resort, and it seems the device got wet. I told her that I would like to see what the device is showing, but she does not have it on hand at the moment since she is working." The consultation is rescheduled. Upon follow-up received on 23Aug2025, the patient's caregiver stated: "I'm giving my daughter some growth hormones. I was given this number to call so I could receive a talk. I'm worried because I've wasted two cartridges. The needle I use to apply it sometimes draws in a lot of air. I have many doubts because it draws in air, and when I place the needle, sometimes it shoots out all at once and the medicine comes out." The nurse stated: "The person in charge of the patient sent the device with someone to a location, and it seems it was transported in a cooler with ice and got wet. The screen became dislocated and is not displaying the numbers correctly".

Causality for "the device was apparently exposed to moisture, as she sent it with another person to a beach resort, and it seems the device got wet/ it was transported in a cooler with ice and got wet", "sometimes it shoots out all at once and the medicine comes out", "the screen became dislocated and is not displaying the numbers correctly" and "the device was apparently exposed to moisture, as she sent it with another person to a beach resort, and it seems the device got wet." was determined associated to device constituent of somatropin (malfunction).