SUSPECT ADVERSE REACTION REPORT

2025A-1401622

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
Masked	COSTA RICA	Masked	Masked	Masked	50	Male	01	Nov	2024

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

1) Lack of effect (After a month and a half of application it lost its effectiveness) (Lack of drug effect (10023610), Drug ineffective (10013709))
(01-Nov-2024 -) - Unknown
2) Product quality complaint (Product quality complaint (10081677), Product quality issue (10069327))
Unknown

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S)INFORMATION

14. SUSPECT DRUG(S)(include generic name)

1) Juvenlife (BTTA>BOTULINUM TOXIN, BOTULINUM TOXIN) (Suspect) (HUA23067)

Continued

20. DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☑ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
UNK	UNK

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☑ NA

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Unknown indication [10057097 - Drug use for unknown indication]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
UNK	UNK

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

No concomitants used/reported

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

UNK

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : ABBOTT GPV
Thomas Nisslein,
Freundallee 9A, Hannover, 30173, GERMANY
pv.qppv@abbott.comand49-3514-5116750

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2025A-1401622
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE
05-Aug-2025	☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE
11-Aug-2025	☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) (Continuation...)

Event Description :

On 05-Aug-2025 a spontaneous report was received from an Other health professional in COSTA RICA concerning a 50 Year(s) old Male patient, who experienced Product quality complaint and Lack of effect (After a month and a half of application it lost its effectiveness), under treatment with Juvenlife. The report was assessed as invalid based on other pharmacovigilance-relevant data only.

The patient initiated treatment on Juvenlife on an unknown date.
Juvenlife was administered. Indication for use was unknown. The lot number was reported as HUA23067. Additional Drug Information: Expiration date: 09/2025.

On 01-Nov-2024 the patient experienced Lack of effect (After a month and a half of application it lost its effectiveness). The event was considered non serious.
On an unknown date the patient experienced Product quality complaint. The event was considered non serious.

The outcome of the event Lack of effect (After a month and a half of application it lost its effectiveness) was unknown.
The outcome of the event Product quality complaint was unknown.

The status of the Juvenlife medication is unknown.

Concomitant medications were not reported.
There were no concomitant diseases reported.
There was no past medical history reported.

Causality assessment for Juvenlife
Reporter causality for the event Lack of effect (After a month and a half of application it lost its effectiveness): Not Reported
Reporter causality for the event Product quality complaint: Not applicable

Pharmacovigilance Comments :

Additional Report Source:
Spontaneous

Patient Additional Information:
Height: 179 Centimeters
Weight: 80 Kilograms

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug	: Juvenlife (BTTA>BOTULINUM TOXIN)
Active Substance	: BOTULINUM TOXIN
Drug Characterization	: Suspect
Lot Number	: HUA23067
Indications	: Unknown indication [10057097 - Drug use for unknown indication]
Action(s) Taken With Drug	: Unknown

Causality

1) Lack of effect (After a month and a half of application it lost its effectiveness) (Lack of drug effect - 10023610, Drug ineffective - 10013709)

Causality as per reporter	: Not Reported
DeChallenge	: Not applicable
ReChallenge	: Not Applicable

2) Product quality complaint (Product quality complaint - 10081677, Product quality issue - 10069327)

Causality as per reporter	: Not applicable
DeChallenge	: Not applicable
ReChallenge	: Not Applicable