SUSPECT ADVERSE REACTION REPORT

2025-14000(0)

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
Masked	COSTA RICA					Female				

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

1) had no therapeutic effect (Lack of drug effect (10023610), Drug ineffective (10013709))
(Asked but Unknown -) - Not applicable
2) Reinjected less than 12 weeks (Off label dosing frequency (10076395), Off label use (10053762))
(Asked but Unknown -) - Not applicable

- ☐ 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) DYSPORT (BOTULINUM TOXIN TYPE A, BOTULINUM TOXIN TYPE A) (Suspect) (Powder for solution for injection) (Unknown)

Cont..

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
1) (120 international unit(s), in 1 Cyclical)	1) Unknown

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

(NA : Not Applicable)

17. INDICATION(S) FOR USE

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

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
(Asked but Unknown - Asked but Unknown)	

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.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : IPSEN Group, Research and Development
70 Rue Balard
Paris, 75015, FRANCE
qppv@ipsen.comand49--1747365171

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2025-14000(0)
24c. DATE RECEIVED BY MANUFACTURER: 09/Jun/2025	24d. REPORT SOURCE: ☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 16/Jun/2025	25a. REPORT TYPE: ☑ INITIAL ☐ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

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

Event Description :

The initial version of this non-serious spontaneous non-AE case was reported by a physician in Costa Rica on 09-Jun-2025 via our licensee partner Biopas Pharma (reference number: 2025-CR-000002) and then transmitted to Ipsen GPS ICSR vendor (via mail) on 12-Jun-2025.

This case was linked to 2025-14001 (same reporter).

It concerns a female patient, who received drug Dysport (Botulinum toxin type A) for unknown indication and experienced had no therapeutic effect (Lack of drug effect) and Reinjected less than 12 weeks (Off label dosing frequency). The patient's height and weight were not reported.

No past disease, underlying condition, past medications, or concomitant medications were reported.

On an unknown date, the patient started single cyclical therapy with Dysport (Botulinum toxin type A), at an unknown strength, at a total dose of 120 U, powder for solution for injection, via unknown route for unknown indication. The batch number and expiration date were not reported.

On unknown date, patient experienced had no therapeutic effect. After 15 days of the first application, the product was reapplied (Reinjected less than 12 weeks).

Action taken with Dysport in response to the events (Reinjected less than 12 weeks, had no therapeutic effect) was not applicable. Dechallenge and rechallenge was not applicable for the events (Reinjected less than 12 weeks, had no therapeutic effect).

At the time of the report, the outcome of the events (Reinjected less than 12 weeks, had no therapeutic effect) was not applicable.

For a conservative approach, as the reporter did not provide causality assessment, the term not reported was coded as no reasonable possibility for non-AEs (Reinjected less than 12 weeks, had no therapeutic effect).

SERIOUSNESS AS PER REPORTER: Non serious (Reinjected less than 12 weeks, had no therapeutic effect)
SERIOUSNESS AS PER COMPANY: Non serious (Reinjected less than 12 weeks, had no therapeutic effect)
CAUSALITY AS PER REPORTER: No reasonable possibility (Reinjected less than 12 weeks, had no therapeutic effect)
CAUSALITY AS PER COMPANY: No reasonable possibility (Reinjected less than 12 weeks, had no therapeutic effect)
EXPECTEDNESS: Unlabelled (Reinjected less than 12 weeks, had no therapeutic effect)

No further information was available.

Company Remarks (Sender's Comments) :

Events drug ineffective, off label use are special situation for which causality cannot be assessed. Considering above mentioned, according to the WHO-UMC method of assessment, the causal relationship between the events and the suspect drug is assessed as unassessable by Ipsen.

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

Product-Reaction Level

1) Drug	: DYSPORT (BOTULINUM TOXIN TYPE A)
Active Substance	: BOTULINUM TOXIN TYPE A
Drug Characterization	: Suspect
Form of Admin	: Powder for solution for injection
Lot Number	: Unknown
Daily Dose	: (120 international unit(s), in 1 Cyclical)
Route of Admin	: Unknown
Indications	: drug use for unknown indication [10057097 - Drug use for unknown indication]
Therapy Dates	: From : Asked but Unknown To :Asked but Unknown
Action(s) Taken With Drug	: Not applicable

Causality

1) had no therapeutic effect (Lack of drug effect - 10023610, Drug ineffective - 10013709)

Causality as per reporter	: No reasonable possibility
Causality as per Mfr	: No reasonable possibility
DeChallenge	: Not applicable

2) Reinjected less than 12 weeks (Off label dosing frequency - 10076395, Off label use - 10053762)

Causality as per reporter	: No reasonable possibility
Causality as per Mfr	: No reasonable possibility
DeChallenge	: Not applicable

Labeling :

Continuation Sheet for CIOMS report

1) had no therapeutic effect
CORE UnLabeled
2) Reinjected less than 12 weeks
CORE UnLabeled