SUSPECT ADVERSE REACTION REPORT

2025-14001(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				☐ PATIENT DIED ☐ LIFE THREATENING ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION ☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY ☐ CONGENITAL ANOMALY ☐ OTHER MEDICALLY IMPORTANT CONDITION

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

1) 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

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)(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) (120 international unit(s), in 1 Cyclical) 2) 120 international unit(s) (120 international unit(s), in 1 Cyclical)	1) Unknown 2) 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	2025-14001(0)
24c. DATE RECEIVED BY MANUFACTURER 09/Jun/2025	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT 13/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, non-AE spontaneous case reported by a physician in Costa Rica at our licensee partner Biopas Pharma Consulting Group (reference number: 2025-CR-000002) on 09-Jun-2025 and then transmitted to Ipsen GPS ICSR vendor on 12-Jun-2025.

This case was cross linked with AER: 2025-14000 (same reporter).

It concerns a female patient (Patient ID: Not Reported), who received Dysport (botulinum toxin type A) for unknown indication and had no therapeutic effect (lack of drug effect) and reinjected less than 12 weeks (off label dosing frequency). Patient's height and weight were not reported.

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

On an unknown date, the patient started single cyclical therapy with Dysport (botulinum toxin type A), Powder for solution for injection, (strength: unknown), at a dose of 120 IU via unknown route for unknown indication. The batch number and expiration date was not reported.

On an unknown date, after 15 days of the first application, the patient re-applied single cyclical therapy with Dysport (botulinum toxin type A), Powder for solution for injection, (strength: unknown), at a dose of 120 IU via unknown route for unknown indication. The batch number and expiration date was not reported.

On an unknown date, patient had no therapeutic effect and reinjected less than 12 weeks.

Action taken with Dysport in response to events no therapeutic effect and reinjected less than 12 weeks was not applicable.

The dechallenge was not applicable for the events no therapeutic effect and reinjected less than 12 weeks.

At the time of this report, the outcome of the events no therapeutic effect and reinjected less than 12 weeks was not applicable.

The reporter did not provide the causality assessment for the events. However as per data handling convention reporter causality was coded no reasonable possibility for non-AE events (no therapeutic effect and reinjected less than 12 weeks).

SERIOUSNESS AS PER REPORTER: Non-Serious (no therapeutic effect and reinjected less than 12 weeks)
SERIOUSNESS AS PER COMPANY: Non-Serious (no therapeutic effect and reinjected less than 12 weeks)
CAUSALITY AS PER REPORTER: No reasonable Possibility (no therapeutic effect and reinjected less than 12 weeks)
CAUSALITY AS PER COMPANY: No reasonable Possibility (no therapeutic effect and reinjected less than 12 weeks)
EXPECTEDNESS: Un-labelled (no therapeutic effect and reinjected less than 12 weeks)

No further information was available.

Company Remarks (Sender's Comments) :

Considering the special situation, the causal relationship between the events drug ineffective, off label use and the suspect drug was assessed as unassessable by Ipsen according to WHO-UMC method of causality assessment

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	:	1) Powder for solution for injection
		2) Powder for solution for injection
Lot Number	:	1) Unknown
		2) Unknown
Daily Dose	:	1) 120 international unit(s) (120 international unit(s), in 1 Cyclical)
		2) 120 international unit(s) (120 international unit(s), in 1 Cyclical)
Route of Admin	:	1) Unknown
		2) Unknown
Indications	:	DRUG USE FOR UNKNOWN INDICATION [10057097 - Drug use for unknown indication]
Therapy Dates	:	1) From : Asked but Unknown To :Asked but Unknown
		2) From : Asked but Unknown To :Asked but Unknown
Action(s) Taken With Drug	:	Not applicable

Causality

Continuation Sheet for CIOMS report

1) 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 :

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

15. DAILY DOSE(S) (Continuation...)

Dosage Text :

Drug 1 :DYSPORT

1) Unknown

2) Unknown