SUSPECT ADVERSE REACTION REPORT

2024-17669(3)

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) ALLERGY (Allergy (10001738), Hypersensitivity (10020751))
(Asked but Unknown -) - Unknown
2) SYNCOPE (Syncope (10042772), Syncope (10042772))
(Asked but Unknown -) - Unknown

- ☐ 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) (500 IU (International Unit), 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) (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
1) (/Jun/2024 - /Jun/2024)	1) 1 Days

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	2024-17669(3)
24c. DATE RECEIVED BY MANUFACTURER: 02/Sep/2024	24d. REPORT SOURCE: ☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 30/May/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 serious spontaneous case was reported by physician in Costa Rica on 02-Sep-2024 and transmitted to partner Biopas Pharma (reference number- 2024-CR-000012) and then transmitted to Ipsen GPS ICSR vendor on 04-Sep-2024.

It concerns a female patient of unknown age who received Dysport (Botulinum toxin type A) for unknown indication and experienced Allergy and syncope. The patient's height and weight were not reported.

No medical history, concurrent condition, past medications, concomitant drug were reported.

On an unknown date in Jun-2024, the patient started cyclical treatment with Dysport (Botulinum toxin type A), at 500 U strength, powder for solution for injection, dose unknown via unknown route for unknown indication. The batch number and expiration date were unknown.

On an unknown date, patient had Allergy and syncope.

Reactions were allergies, itchy nose, sneezing, nasal pruritus, eye irritation and most importantly decompensation on several occasions equal to syncope.

No lab tests and no corrective treatment were reported.

Action taken with Dysport in response to the events (Allergy and syncope) was not reported.

At the time of this report, outcome of the events (Allergy and syncope) was unknown.

The reporter did not provide the causality assessment for the events (Allergy and syncope). However, as per data handling guidance, reporter causality coded as reasonable possibility.

SERIOUSNESS AS PER REPORTER: serious- other IME (Allergy, syncope)
SERIOUSNESS AS PER COMPANY: serious- other IME (Allergy, syncope)
CAUSALITY AS PER REPORTER: Reasonable possibility (Allergy, syncope)
CAUSALITY AS PER COMPANY: No reasonable possibility (syncope), Reasonable possibility (allergy)
EXPECTEDNESS: Unlabelled (syncope), labelled (allergy)

No further information was available.

Significant correction done on 24-Sep-2024 with previous LRD 02-Sep-2024 to Update company causality to related for event allergy and to remove events sneezing, irritation of eyes, and nasal pruritus.

Amendment information of this spontaneous serious case was reported by a physician in Costa Rica on 02-Sep-2024 via licensee partner Biopas Pharma (Reference number: 2024-CR-000012) and transmitted to Ipsen GPS ICSR vendor (via mailbox) on 09-May-2025.
As per the information received findings identified in the recent audit and partner send a correction of this case. USA labeling updated from label to Unlabeled for the event syncope.
Minor change was performed on 27-May-2025, to distribute the correction case to partner Biopas.

Amendment information of this spontaneous serious case was reported by a physician in Costa Rica on 02-Sep-2024 via licensee partner Biopas Pharma (Reference number: 2024-CR-000012) and transmitted to Ipsen GPS ICSR vendor (via mailbox) on 27-May-2025.
As per the information received findings identified in the recent audit and partner send a correction of this case. Removed event stupor and these updates have been incorporated into the narrative above.

Company Remarks (Sender's Comments) :

There is limited information on time to onset date and details of the event syncope, any primordial risk factor, relevant medical history, concomitant medications, relevant investigations and treatment received. Based on the available information, according to the WHO-UMC method of assessment, the causal relationship between these event and suspect drug Dysport was assessed as conditional by Ipsen it look possible complication to concurrent Allergic reaction.

Considering known safety profile of drug therapy and plausible temporal association hence according to the WHO-UMC assessment method, causal relationship between Hypersensitivity and suspect drug Dysport was assessed as possible by Ipsen.

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

Product-Reaction Level

1) Drug : DYSPORT (BOTULINUM TOXIN TYPE A)

Continuation Sheet for CIOMS report

Active Substance	:	BOTULINUM TOXIN TYPE A
Drug Characterization	:	Suspect
Form Strength	:	500 IU (International Unit)
Form of Admin	:	Powder for solution for injection
Lot Number	:	Unknown
Daily Dose	:	(in 1 Cyclical)
Route of Admin	:	Unknown
Indications	:	DRUG USE FOR UNKNOWN INDICATION [10057097 - Drug use for unknown indication]
Therapy Dates	:	From : /Jun/2024 To :/Jun/2024
Therapy Duration	:	1 Days
Action(s) Taken With Drug	:	Unknown

Causality

1) ALLERGY (Allergy - 10001738, Hypersensitivity - 10020751)

Causality as per reporter	:	Reasonable possibility
Causality as per Mfr	:	Reasonable possibility
DeChallenge	:	Not applicable
ReChallenge	:	Not Applicable

2) SYNCOPE (Syncope - 10042772, Syncope - 10042772)

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

Labeling :

1) ALLERGY	
CORE	Labeled
2) SYNCOPE	
CORE	UnLabeled