# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

| 1.PATIENT INITIALS (First, Last) | 1a. COUNTRY | 2. DATE OF BIRTH | 2a. AGE | 3. SEX | 4-6 REACTION ONSET |
|---|---|---|---|---|---|
| LS | Guatemala | 19-May-1973 | 51 Year(s) | Female | 9-Apr-2025 |

8-12. CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED IN-PATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ OTHER MEDICALLY SIGNIFICANT EVENT

7. + 13. DESCRIBE REACTION(S) (including relevant tests / lab data) *[further details on Continuation Page]*

| Events | From | To | Duration |
|---|---|---|---|
| Lack of effect of the product when applied to the forehead ((LLT) Lack of drug effect) | 9-Apr-2025 | UNK | UNK |

Initial information (22-MAY-2025)
) City of occurrence: No ref.

Reporter reports that the female patient (Caucasian race) went to the clinic for Toxin administration, on 09/Apr./2025 165 units were placed on the forehead, at the time of routine review 21 days later it was found that the product has had no effect. The reporter considered the event as a

## II. SUSPECT DRUG(S) INFORMATION

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

1) DYSPORT (CLOSTRIDIUM BOTULINUM TYPE A TOXIN HEMAGGLUTININ COMPLEX);MAH Ref PF-33078-2019;Lot# 004458;Formulation Powder for solution for injection

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

15. DAILY DOSE(S)
1) 165 IU

16. ROUTE(S) OF ADMINISTRATION
1) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? YES ☐ NO ☐ NA ☒

17. INDICATION(S) FOR USE 1) Unknown

18. THERAPY DATES (From/To)
1) From: 9-Apr-2025 To:

19. THERAPY DURATION
1) Unknown

## III. CONCOMITANT DRUG(S) AND HISTORY

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

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

Medical History:
(Unknown (LLT) UNK)

## IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
IPSEN BIOPHARM LIMITED
Guatemala

24b. MFR CONTROL No.
2025-GT-000004

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

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☐ HEALTH PROF ☒ * OTHER

DATE OF THIS REPORT
30-May-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOW-UP

Primary Reporter:
G M
Guatemala

Y J
Guatemala

PV Safety Group:
Biopas
Calle 127A #53A-45

*[further details on Continuation Page]*

* Medical Physician

## SUSPECT ADVERSE REACTION REPORT
Continuation Page

| MANUFACTURER CONTROL NUMBER | 2025-GT-000004 |
|---|---|

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

non-serious reaction. The reporter did not report the outcome of the event. Reporter reported that the patient had previously administered the product on 03-Sep-2024 and had the expected paralysis effect, but did not report dose, route, number of therapies, site of administration.

Follow-up #1 (29-MAY-2025)

City of occurrence: No reference.

Reporter reports the patient's initials, date of birth and age, so the information is updated.

[Site Details - continued]

Torre 2, Oficina 1202
Bogota 111121
Colombia

26. REMARKS

Clinical trial

Clinical trial patient number: