SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
*****	Honduras - HN	**	***	****	25 Years	Female				2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

The doctor advised to take the 30 sachets in a row [Product prescribing issue (10080459)*], Outcome: unknown

This initial invalid spontaneous case was received on 12-Mar-2025 from a consumer in Honduras and concerns children of an unknown age and gender. The patient's medical history and concomitant medications were not reported. It was reported that the patients have been using Broncho-Vaxom for years and it has always been as indicated on the package leaflet, 10 days in a row (…)

(Continued on Additional Information page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT PRODUCT(S) INFORMATION

14. SUSPECT PRODUCT(S) (include generic name)
#1) Broncho-Vaxom (OM-85) - Batch/Lot #: 2300305

15. DAILY DOSE(S)
#1)

16. ROUTE(S) OF ADMINISTRATION
#1)

17. INDICATION(S) FOR USE
#1) To strengthen immune system [Immune enhancement therapy (10064058)*]

18. THERAPY DATE(S) (from/to)
#1) 01-Mar-2025 to --

19. THERAPY DURATION
#1)

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ Yes ☐ No ☐ N/A

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ Yes ☐ No ☒ N/A

III. CONCOMITANT PRODUCT(S) AND HISTORY

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

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
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Broncho vaxom (Bacteria lysate nos), [Immune enhancement therapy (10064058)*]

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
OM Pharma Ltd.
OM Pharma
Rue du Bois-du-Lan 22, Meyrin
Geneva, 1217
Switzerland (…)

25b. NAME AND ADDRESS OF REPORTER
***** ***** ***** Consumer or other non health professional
*****
*****
***** (…)

24b. MFR CONTROL NO.
HN-OM-OM-009430

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

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL

DATE OF THIS REPORT
19-May-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP

26. REMARKS

I. Reaction Information
7 + 13 DESCRIBE REACTIONS(S) (including relevant tests/lab data): on an empty stomach, 20 days off and then start again, for 3 months, to strengthen immune system.
On an unspecified date, the patient was recommended to start a treatment with Broncho-Vaxom (OM-85) sachets (batch number, expiration date, dosage and route of administration not reported), 30 sachets in a row (PT: Product prescribing issue), to strengthen immune system.
Action taken with Broncho-Vaxom was unknown.
The outcome of the event Product prescribing issue was unknown.

Significant follow up information was received on 02-May-2025
The case was considered as a valid case as the patient’s information was provided. The patient was a 25-years-old female (reference case: OM-2025-HN-0001).
On 01-Mar-2025, the patient started the 3rd month of the treatment (batch number: 2300305, expiration date: Dec-2027).
It was reported that the mother of the patient followed the indications according to the product leaflet.
Action taken with Broncho-Vaxom was unknown.
The seriousness and causality assessment of the event was not reported.
This case is linked to another case OM-009479 reported for the patient’s sibling by the same reporter.

Company assessment:
The event Product prescribing issue is classified as a special situation and as non-serious as per company data entry conventions.
No further information is expected, the case has been closed.

IV. Manufacturer Information
24a. Name and Address of Manufacturer: OM Pharma Ltd.
OM Pharma
Rue du Bois-du-Lan 22, Meyrin
Geneva, 1217
Switzerland
safety@ompharma.com

25b. Name and Address of Reporter: ***** ***** ***** Consumer or other non health professional
*****
*****
*****
Honduras

Assessment Results
- Broncho-Vaxom ↔ Product prescribing issue, Market Authorization Holder (MAH), WHO-UMC causality assessment, Unassessable/Unclassifiable
- Broncho-Vaxom ↔ Product prescribing issue, Non-Health Care Professional, WHO-UMC causality assessment, Unassessable/Unclassifiable