CIOMS FORM

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
PRIVACY	COSTA RICA		PRIVACY		47 Years	Female	68.00 kg			2024

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

Other Serious Criteria: Medically Significant
pneumonia [Pneumonia]
bronchitis [Bronchitis]
vision has deteriorated [Visual impairment]

Case Description: Study ID: 828652-My Healthy Journey

Study description: Trial title: This is a 40 weeks digital patient support program with focus on exercise, motivation, nutrition & maintaining strategies (only for patients under Liraglutide 3.0 mg).

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 1.2 mg, qd

16. ROUTE(S) OF ADMINISTRATION
#1) Subcutaneous

17. INDICATION(S) FOR USE
#1) Weight loss (Weight control)

(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) SEP-2023 / Unknown

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)

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

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Insulin resistance (Insulin resistance)
Unknown to Ongoing	Current Condition	COVID-19 (COVID-19)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Novo Nordisk A/S
Lise Grimmeshave
Vandtaarnsvej 114
Soeborg, DK-2860 DENMARK
Phone: +45 44448888

26. REMARKS
Medically Confirmed: No

24b. MFR CONTROL NO.
1442385

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
26-MAY-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
03-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1442385

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

This serious Solicited Report from COSTA RICA was reported by a Consumer as "pneumonia(Pneumonia)" beginning on MAR-2025 , "bronchitis(Bronchitis)" beginning on MAR-2025 , "vision has deteriorated(Visual impairment)" beginning on 2024 and concerned a 47 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from SEP-2023 for "Weight loss", "insulin deficiency",

Patient's height: 170 cm.
Patient's weight: 68 kg.
Patient's BMI: 23.52941180.

Dosage Regimens:
Saxenda: ??-SEP-2023 to Not Reported, Not Reported to Not Reported;

Current Condition included Insulin insufficiency, COVID, pneumonia three times.

Treatment medications included VITAMIN D COLECALCIFEROL.

On an unknown date in 2024 the patient felt that her vision has deteriorated. Annual exams(Investigations) were performed annually results not provided for treatment of the event.

On an unspecified date in MAR-2025 the patient experienced flu which led to pneumonia and bronchitis. The patient was taking daily nebulization with Vitamin D for the treatment of the event.

The Batch Numbers for Saxenda was requested.

Action taken to Saxenda was reported as Product discontinued.

The outcome for the event "pneumonia(Pneumonia)" was Recovering/resolving.
The outcome for the event "bronchitis(Bronchitis)" was Recovering/resolving.
The outcome for the event "vision has deteriorated(Visual impairment)" was Recovering/resolving.

Reporter's causality (Saxenda) -
pneumonia(Pneumonia) : Possible
bronchitis(Bronchitis) : Possible
vision has deteriorated(Visual impairment) : Possible

Company's causality (Saxenda) -
pneumonia(Pneumonia) : Unlikely
bronchitis(Bronchitis) : Unlikely
vision has deteriorated(Visual impairment) : Unlikely

Company Comment:

Pneumonia, Bronchitis and Visual impairment are assessed as unlisted events according to Novo Nordisk current reference safety information (CCDS) on Saxenda.

Pneumonia is a respiratory infection that inflames the air sacs in one or both lungs. These air sacs, called alveoli, can fill with fluid or pus, making it difficult to breathe. Pneumonia is caused by various infectious agents, including bacteria, viruses, and fungi, and can range in severity. Infants, young children, older adults, individuals with weakened immune systems, use of acid-suppressing medications, those who have been on mechanical ventilation, been in crowded, unhygienic environment and have travel history/exposure to affected individuals are at higher risk.

Patients underlying medical history of Insulin insufficiency, COVID, pneumonia three times along with older age are assessed as significant possible confounding factors for the Pneumonia.

Considering the infectious nature of event, above factors, available information and safety profile of suspect product, causality for the Pneumonia is evaluated as Unlikely related to suspect product.

This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Investigation		

Mfr. Control Number: 1442385

ADDITIONAL INFORMATION

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		On an unknown date exam(Investigation) were performed annually results not provided.		

13. Relevant Tests

On an unknown date exam(Investigation) were performed annually results not provided.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #1	1.2 mg, qd; Subcutaneous	Weight loss (Weight control) insulin deficiency (Insulin resistance)	SEP-2023 / Unknown; Unknown
#1) Saxenda (liraglutide 6 mg/mL) Solution for injection, 6 mg/mL; Regimen #2	2.4 mg, qd; Subcutaneous	Weight loss (Weight control) insulin deficiency (Insulin resistance)	Unknown; Unknown

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Current Condition	Pneumonia (Pneumonia);