SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		45 Years	Female	112.00 kg	20	APR	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
inflammation in pancreas [Pancreatitis]

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).

Patient's height: 167 cm.

(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

15. DAILY DOSE(S)
#1) 0.6 mg, qd

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

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

18. THERAPY DATES(from/to)
#1) 18-APR-2024 / 21-APR-2024

19. THERAPY DURATION
#1) 3 days

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

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

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

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.
1450823

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

24c. DATE RECEIVED BY MANUFACTURER
04-JUN-2025

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

DATE OF THIS REPORT
12-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 1450823

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Patient's weight: 112 kg.

Patient's BMI: 40.15920260.

This serious Solicited Report from COSTA RICA was reported by a Consumer as "inflammation in pancreas(Pancreatic inflammation)" beginning on 20-APR-2024 and concerned a 45 Years old Female patient who was treated with Saxenda (liraglutide 6 mg/mL) from 18-APR-2024 to 21-APR-2024 for "weight loss",

Dosage Regimens:
Saxenda: 18-APR-2024 to 21-APR-2024;

Medical history was not provided.

Treatment medications included - FAMOTIDINE.

On 20-Apr-2024, the patient experienced very severe pancreatic inflammation and stomach became very swollen. This required discontinuation of the medication and hospital visits. The patient underwent an ultrasound(Ultrasound scan) in February (result not provided). The reaction was identified as a side effect since the patient has no underlying conditions.

Batch Number of Saxenda was requested.

Action taken to Saxenda was reported as Product discontinued due to AE.

On OCT-2024 the outcome for the event "inflammation in pancreas(Pancreatic inflammation)" was Recovered.

Reporter's causality (Saxenda) -
inflammation in pancreas(Pancreatic inflammation) : Possible

Company's causality (Saxenda) -
inflammation in pancreas(Pancreatic inflammation) : Possible

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	FEB-2025	Ultrasound scan On an unknown date, the patient underwent Ultrasound (result not reported)		

13. Relevant Tests

On an unknown date, the patient underwent Ultrasound (result not reported)