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	EL SALVADOR		PRIVACY		54 Years	Female	68.00 kg	17	APR	2025

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

Nausea [Nausea]
Vomiting [Vomiting]
Abdominal pain [Abdominal pain]

Case Description: Patient Demographics: 54 Years old Female

Event(s): Nausea, Vomiting, Abdominal pain

Suspect Product(s) (Name, IFU): trulicity 1.5mg (dulaglutide) for treatment of Type 2 diabetes mellitus

(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

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Trulicity 1.5mg (Dulaglutide) Solution for injection in pre-filled pen, 1.5 mg

15. DAILY DOSE(S)
#1) 1.5 mg, weekly (1/W)

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

17. INDICATION(S) FOR USE
#1) Type 2 diabetes mellitus (Type 2 diabetes mellitus)

18. THERAPY DATES(from/to)
#1) 10-APR-2025 / Unknown

19. THERAPY DURATION
#1) Unknown

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 to Ongoing	Medical Condition	Type 2 diabetes mellitus (Type 2 diabetes mellitus)
Unknown to Ongoing	Medical Condition	Hypertension (Hypertension)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Eli Lilly & Company

26. REMARKS

24b. MFR CONTROL NO.
SV202507022278

24c. DATE RECEIVED BY MANUFACTURER
21-JUL-2025

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

DATE OF THIS REPORT
25-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Action(s) Taken: trulicity 1.5mg (dulaglutide) - Drug Discontinued

Event Outcome(s): Nausea (Unknown), Vomiting (Unknown), Abdominal pain (Unknown)

Reporter's Opinion of Relatedness: trulicity 1.5mg (dulaglutide) - Nausea (Yes) , Vomiting (Yes) , Abdominal pain (Yes)

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
Unknown to Ongoing	Medical Condition	Diabetic neuropathy (Diabetic neuropathy);