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		37 Years	Female	Unk		JUN	2025

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

Very sleepy the day after the application [Somnolence]
High fatigue the day after application [Fatigue]

Case Description: Patient Demographics: 37 Years old Female

Event(s): Very sleepy the day after the application, High fatigue the day after application

Suspect Product(s) (Name, IFU): trulicity 1.5mg (dulaglutide) for treatment of DM2

(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) DM2 (Type 2 diabetes mellitus)

18. THERAPY DATES(from/to)
#1) JUN-2025 / Ongoing

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)

IV. MANUFACTURER INFORMATION

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

26. REMARKS

24b. MFR CONTROL NO.
SV202507006710

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

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

DATE OF THIS REPORT
09-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) - No Change

Event Outcome(s): Very sleepy the day after the application (Unknown), High fatigue the day after application (Unknown)

Reporter's Opinion of Relatedness: trulicity 1.5mg (dulaglutide) - Very sleepy the day after the application (Yes) , High fatigue the day after application (Yes)