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		60 Years	Male	Unk		Unk	

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

Very ill [Illness]

Case Description: This spontaneous case, reported by a consumer who contacted the company via a business partner to report an adverse event, concerned a 60-Year-old (at the time of initial report) male patient of an unknown origin.

Medical history and concomitant medications were not provided.

The patient received dulaglutide (Trulicity), via an unspecified

(Continued on Additional Information Page)

- ☐ 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) Unknown, 1.5 mg
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 1.5 mg, unknown

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

17. INDICATION(S) FOR USE
#1) Drug use for unknown indication (Produ
(Continued on Additional Information Page)

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

18. THERAPY DATES(from/to)
#1) 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

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Eli Lilly Interamerica Inc (AR Branch)
Tronador 4890 - Piso 12
Buenos Aires, Capital Federal CP: 1430 ARGENTINA
Phone: 54 1145464000

26. REMARKS

24b. MFR CONTROL NO.
CR202507012984

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
16-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: CR202507012984

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

disposable device, 1.5 mg, at an unknown frequency, via an unknown route of administration, for an unknown indication, beginning on an unknown date. On an unknown date, while on dulaglutide therapy, he was very ill, due to which he was hospitalized. Information regarding further hospitalization and discharge details, the corrective treatment, the outcome of the event, and dulaglutide therapy status was not provided.

The initial reporting consumer related the event with dulaglutide therapy.

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) Trulicity 1.5mg (Dulaglutide) Unknown, 1.5 mg; Regimen #1	1.5 mg, unknown; Unknown	Drug use for unknown indication (Product used for unknown indication)	Unknown; Unknown