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		43 Years	Female	Unk		Unk	

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

THE EXPIRATION DATE WAS 30APR2025 / THE TREATMENT HAS NOT BEEN INTERRUPTED [Expired drug administered]
THE PHARMACY REMOVED THE EXPIRATION DATES [Expired drug dispensed]

Case Description: This is a spontaneous report received from a Consumer or other non HCP from License Party(Bristol-Myers Squibb). Other Case identifier(s): CR-BRISTOL-MYERS SQUIBB COMPANY-2025-085822 (BRISTOL-MYERS SQUIBB COMPANY).

(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) Eliquis (APIXABAN) Unknown {Lot # HJ6178; Exp.Dt. 30-APR-2025}

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

15. DAILY DOSE(S)
#1) UNK

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

17. INDICATION(S) FOR USE
#1) Unknown

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

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

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
Pfizer S.A.
Laura Arce Mora
Avenida Escazú, Torre Lexus, piso 7. Escazú
San Jose, COSTA RICA

26. REMARKS

24b. MFR CONTROL NO.
202500120607

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

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

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

DATE OF THIS REPORT
18-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

This case was received via {BP} Pfizer Inc(Reference number: 202500120607) Information was received from a Consumer or other non health professional concerning a 43 Year(s) old Female patient, who received Suspect product APIXABAN from unknown start date) for PRODUCT USED FOR UNKNOWN INDICATION, lot number: HJ6178;. On an unknown date, the patient had expired product administered (the expiration date was 30apr2025 / the treatment has not been interrupted), which was considered non-serious. It is unknown if treatment was provided. The outcome of the expired product administered was unknown. On an unknown date, the patient had product dispensing error (the pharmacy removed the expiration dates), which was considered non-serious. It is unknown if treatment was provided. The outcome of the product dispensing error was unknown. As a result of the event(s), the dose of APIXABAN was not changed. Concomitant medications were not reported. The reporter did not provide a causality assessment for events expired product administered and product dispensing error to APIXABAN. Tracking of Changes: 12-Jun-2025: Initial information was received.

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