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	COSTA RICA		PRIVACY		Unk	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)

RAISED THE ENZYMES OF THE LIVER [Raised liver enzymes]

Case Description: This is a spontaneous report received from a Consumer or other non HCP from medical information team and License Party (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
#2) ADALIMUMAB (ADALIMUMAB)

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 5 mg	#1) Unknown
#2) 4 mg	#2) Unknown

17. INDICATION(S) FOR USE
#1) Pulmonary Thrombosis (Pulmonary thrombosis)
#2) axial spondyloarthritis (Axial spondyloarthritis)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#1) Unknown
#2) Unknown	#2) 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		

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.
202500108533

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

24c. DATE RECEIVED BY MANUFACTURER
26-MAY-2025

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

DATE OF THIS REPORT
04-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Other Case identifier(s): CR-BRISTOL-MYERS SQUIBB COMPANY-2025-077733 (BRISTOL-MYERS SQUIBB COMPANY).

This case was received via {BP} Pfizer Inc(Reference number: 202500108533) Information was received from a Consumer or other non health professional concerning a Female patient, who received Suspect product APIXABAN 5 milligram(s)from unknown start date) for Pulmonary Thrombosis, lot number: Unknown;; Suspect product EXTERNAL-ADALIMUMAB 4 milligram(s)from unknown start date) for axial spondyloarthritis, lot number: Unknown;. On an unknown date, the patient had hepatic enzyme increased (raised the enzymes of the liver), which was considered non-serious. It is unknown if treatment was provided. The outcome of the hepatic enzyme increased was unknown. The action taken with APIXABAN medication was unknown. The action taken with EXTERNAL-ADALIMUMAB medication was unknown. Concomitant medications were not reported. The reporter considered event hepatic enzyme increased related to APIXABAN. The reporter considered event hepatic enzyme increased related to EXTERNAL-ADALIMUMAB. Consent to contact the consumer or other non health professional for follow-up information was denied, or it was indicated that no further information is available. Tracking of Changes: 26-May-2025: Initial information was received.

Eliquis is under agreement with Bristol-Myers Squibb.