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			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year				Day	Month	Year	
PRIVACY	PANAMA		PRIVACY		58 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)

Other Serious Criteria: Medically Significant
blisters on the soles of her feet and hands [Blisters]
bleeding [Bleeding]
high blood pressure [Blood pressure high]
intense itching in the hands and feet [Itching]
distress [Emotional distress]

Case Description: This is a spontaneous report received from a Consumer or other non HCP, Program ID: 164974.

(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) Inlyta (AXITINIB) Film-coated tablet {Lot # LY2167; Exp.Dt. MAY-2027}

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) 5 mg, 2x/da (Continued on Additional Information Page)

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) 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)
#1) PEMBROLIZUMAB (PEMBROLIZUMAB) ; Unknown

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.
PV202500062402

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
26-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

A 58-year-old female patient received axitinib (INLYTA), (Lot number: LY2167, Expiration Date: May2027) at 5 mg 2x/day (5 mg, 2x/day (one in the morning and another in the afternoon)). The patient's relevant medical history was not reported. Concomitant medication(s) included: PEMBROLIZUMAB. The following information was reported: BLISTER (medically significant), outcome "unknown", described as "blisters on the soles of her feet and hands"; HAEMORRHAGE (non-serious), outcome "unknown", described as "bleeding"; HYPERTENSION (non-serious), outcome "unknown", described as "high blood pressure"; PRURITUS (non-serious), outcome "unknown", described as "intense itching in the hands and feet"; EMOTIONAL DISTRESS (non-serious), outcome "unknown", described as "distress". The patient's husband reported that the oncology treatment was working, as a recent CAT scan had shown a decrease in the lesions. However, the patient then developed blisters on the soles of her feet and hands, a side effect of the treatment according to the oncologist, which caused her distress. Although the oncologist had already administered medication (injectables/IV therapy), the husband asked if they knew of any cream or treatment for those blisters. He mentioned that the patient had previously experienced bleeding and high blood pressure (already medicated). A week earlier, the doctor had suggested warm water baths for intense itching in her hands and feet, but the blisters appeared afterward. He appreciated any suggestions to help remove the blisters from his wife. The patient underwent the following laboratory tests and procedures: Computerised tomogram: decrease in the lesions. The action taken for axitinib was unknown. Therapeutic measures were taken as a result of blister, haemorrhage, hypertension.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Computerised tomogram	decrease in the lesions	

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) Inlyta (AXITINIB) Film-coated tablet {Lot # LY2167; Exp.Dt. MAY-2027}; Regimen #1	5 mg, 2x/day (one in the morning and another in the afternoon); Unknown	Unknown	Unknown; Unknown