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	GUATEMALA		PRIVACY		75 Years	Male	Unk		Unk	

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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
Xeljanz sent me to the hospital / pneumonia because it lowered the autoimmune system a lot [Pneumonia]

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

A 75-year-old male patient received tofacitinib citrate (XELJANZ), at 5 mg 2x/day. The patient's relevant medical history included: "rheumatoid arthritis" (unspecified if ongoing).

(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) Xeljanz (TOFACITINIB CITRATE) Tablet

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

15. DAILY DOSE(S)
#1) 5 mg, 2x/day

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)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

From/To Dates	Type of History / Notes	Description
Unknown	Relevant Med History	Rheumatoid arthritis (Rheumatoid arthritis)

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.
PV202500052344

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

24c. DATE RECEIVED BY MANUFACTURER
28-APR-2025

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

DATE OF THIS REPORT
05-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's concomitant medications were not reported. The following information was reported: PNEUMONIA (hospitalization, medically significant), outcome "unknown", described as "Xeljanz sent me to the hospital / pneumonia because it lowered the autoimmune system a lot". Patient indicated: "Xeljanz sent me to the hospital. I do not know what happened, but the doctor, not the rheumatologist, knows what went wrong. The thing is that it caused me a big infection, pneumonia because it lowered the autoimmune system a lot, which is precisely what Xeljanz works for. Today I am using a biological medicine called Symphony, what happens is that the pain of rheumatoid arthritis went on, on, on and on and the degeneration that produces that arthritis also followed. So, the medication no, it did not work, it did not stop the effect and we had to look for other alternatives, I even broke off relations with the Dr. because the pulmonologists did not agree, because they insisted that, because part of what I was taking the product had been the effect of stopping the pneumonia. And then there was a very strong friction there with them. I tell them, my idea is not to look for lawsuits, my idea is to heal myself, it is to be healthy, to be pain-free. That is why I, well, I looked for the best of the best that was Pfizer's Xeljanz, it is a very, very proven and very good product. But unfortunately not all bodies are the same and no, it did not work for me." Patient is currently with Symphony. The action taken for tofacitinib citrate was unknown.

Case Comment: Considering the plausible temporal relationship and increased risk from immunosuppressive nature of Tofacitinib, the contributory role of suspect drug cannot be completely ruled out for the event pneumonia.