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		78 Years	Female	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)

terrible arm pain [Pain in arm]
a lot of cramps in my feet [Foot cramps]
cough [Cough]

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

A 78-year-old female patient received palbociclib (PALBOCICLIB), (Lot number: SK751, Expiration Date: Jul2027) at 125 mg daily; anastrozole (ARIMIDEX).

(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) Palbociclib (PALBOCICLIB) Unknown {Lot # SK751; Exp.Dt. JUL-2027}
#2) ARIMIDEX (ANASTROZOLE)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 125 mg, daily	#1) Unknown
#2)	#2) Unknown

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

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

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

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.
PV202500056646

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
13-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history included: "breast surgery" (unspecified if ongoing). The patient's concomitant medications were not reported.
The following information was reported: PAIN IN EXTREMITY (non-serious), outcome "unknown", described as "terrible arm pain"; MUSCLE SPASMS (non-serious), outcome "unknown", described as "a lot of cramps in my feet"; COUGH (non-serious), outcome "unknown". The action taken for palbociclib was unknown.

Additional information: Patient reported she realized that that other one called "Arimidex", is the one that is giving me those great pain in an arm that had long ago been discarded many years and many years ago foot cramps. Then she realized that, she has always given me Palbociclib and the Arimidex together, reported that she had taken it, she has had surgery on her chest, on that side, and her arm it's like more sensitive, so it's a terrible pain. Patient reported that didn't take treatment for a month.
That's when she realized that the cramps and pain in my arm went away.