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	COSTA RICA		PRIVACY		76 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
suffered a fall / going with the patient urgently to a medical appointment [Fall]
was experiencing cognitive decline [Cognitive deterioration]

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

A 76-year-old female patient received desvenlafaxine succinate monohydrate (PRISTIQ), since 2017 at 100 mg 1x/day for depression.

(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) Pristiq (DESVENLAFAXINE SUCCINATE MONOHYDRATE) Prolonged-release tablet

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

15. DAILY DOSE(S)
#1) 100 mg, 1x/day

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

17. INDICATION(S) FOR USE
#1) depression (Depression)

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

18. THERAPY DATES(from/to)
#1) 2017 / 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) EXELON [RIVASTIGMINE] (RIVASTIGMINE) ; Unknown
#2) SOMAZINA [CITICOLINE] (CITICOLINE) ; 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.
PV202500020509

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

24c. DATE RECEIVED BY MANUFACTURER
17-JUL-2025

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

DATE OF THIS REPORT
22-JUL-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history was not reported. Concomitant medication(s) included: EXELON [RIVASTIGMINE]; SOMAZINA [CITICOLINE].
The following information was reported: FALL (medically significant), outcome "unknown", described as "suffered a fall / going with the patient urgently to a medical appointment"; COGNITIVE DISORDER (non-serious), outcome "unknown", described as "was experiencing cognitive decline". The patient was going to an appointment since she suffered a fall. The patient's caregiver indicated that the patient was taking the medication Pristiq for depression and was experiencing cognitive decline. The action taken for desvenlafaxine succinate monohydrate was unknown.

No follow-up attempts are possible.

Follow-up (17Jul2025): This is a spontaneous follow-up report received from a Consumer or other non-HCP, Program ID: 164974. Updated information included: Product data (suspect product indication, start date, and dosing regimen updated, concomitant medications added); reaction data (new event "was experiencing cognitive decline" added); clinical course.