CIOMS FORM

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		Unk	Male	Unk	01	JAN	2000

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Other Serious Criteria: Medically Significant

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Anaphylactic shock [Anaphylactic shock]	FORXIGA	Yes	No	Related	

(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
- ☐ CONGENITAL ANOMALY
- ☒ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) FORXIGA (DAPAGLIFLOZIN) Film-coated tablet

15. DAILY DOSE(S)
#1) 10 milligram, qd

16. ROUTE(S) OF ADMINISTRATION
#1) Oral use

17. INDICATION(S) FOR USE
#1) Chronic Kidney Disease (Chronic kidney disease)

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

19. THERAPY DURATION
#1) 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 to Ongoing	Indication	Chronic kidney disease (Chronic kidney disease)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
AstraZeneca
Serban Ghiorghiu
1 Medimmune Way
Gaithersburg, Maryland 20878 UNITED STATES
Phone: +1 301-398-0000

26. REMARKS
World Wide #: CR-ASTRAZENECA-202507CAM020017CR
Case References: CR-AstraZeneca-CH-00917309A

24b. MFR CONTROL NO.
202507CAM020017CR

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

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

DATE OF THIS REPORT
28-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

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

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A spontaneous report has been received from a physician concerning a male patient (age not provided).

No medical history and No concomitant products were reported.

On an unknown date the patient started treatment with Forxiga (dapagliflozin) 10 milligram qd, Oral use, for chronic kidney disease.

On 01-JAN-00, the patient experienced anaphylactic shock (preferred term: Anaphylactic shock).

The patient recovered from the event(s) anaphylactic shock on an unspecified date.

The event was considered serious due to Medically Significant.

The reporter considered that there was a reasonable possibility of a causal relationship between Forxiga and the following event(s): anaphylactic shock.

Company Clinical Comment: Anaphylactic shock is not listed in the company core data sheet of dapagliflozin. Due to limited information on circumstances leading to event, start date of suspect drug, clinical course, treatment provided, risk factors, relevant medical history, concurrent conditions and concomitant medications, detailed diagnostic and etiologic workup, the evaluation did not find the evidence to suggest a causal relationship between the event and suspect drug.