CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		Unk	Male	Unk		Unk	

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

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Fournier's gangrene [Fournier's gangrene]	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) UNK

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

17. INDICATION(S) FOR USE
#1) (Not Coded)

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

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-202504CAM027451CR
Case References: CR-AstraZeneca-CH-00860683A

24b. MFR CONTROL NO.
202504CAM027451CR

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

NAME AND ADDRESS WITHHELD.

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

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

DATE OF THIS REPORT
06-MAY-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A spontaneous report has been received from a physician. The report concerns a male elderly patient.

No medical history was reported. No concomitant products were reported.

On an unknown date, the patient started treatment with Forxiga (dapagliflozin) UNK.

On an unknown date, the patient experienced fournier's gangrene (preferred term: Fournier's gangrene).

At the time of reporting, the event fournier's gangrene was improving.

The reporter assessed the event of fournier's gangrene as serious due to seriousness criteria of Hospitalized.

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

Company Clinical Comment: Fournier's gangrene is not listed in the company core data sheet of dapagliflozin. Due to limited information on underlying comorbidities, onset date and outcome of the event, therapy start date, treatment undertaken, clinical course, circumstances leading to the event, past medical history and concomitant medications, detailed diagnostic and etiological workup, the evaluation did not find evidence to suggest a causal relationship between event and suspect drug