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	EL SALVADOR		PRIVACY		Unk	Unk	Unk		Unk	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

Patient age group: infant [Off label use in unapproved age group]

Case Description: This is a spontaneous report received from a Physician.

An infant patient received avibactam sodium, ceftazidime pentahydrate (AVIBACTAM SODIUM, CEFTAZIDIME PENTAHYDRATE), from May2025 to May2025 for abdominal infection.

(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

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Avibactam Sodium, Ceftazidime Pentahydrate (AVIBACTAM SODIUM, CEFTAZIDIME PENTAHYDRATE)
(Continued on Additional Information Page)

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

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK	#1) Unknown

17. INDICATION(S) FOR USE
#1) Complicated intra-abdominal infection (Abdominal infection)

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

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) MAY-2025 / MAY-2025	#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

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.
202500116896

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

24c. DATE RECEIVED BY MANUFACTURER
06-JUN-2025

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

DATE OF THIS REPORT
11-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 202500116896

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: OFF LABEL USE (non-serious), outcome "unknown", described as "Patient age group: infant". The action taken for avibactam sodium, ceftazidime pentahydrate was unknown.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Avibactam Sodium, Ceftazidime Pentahydrate (AVIBACTAM SODIUM, CEFTAZIDIME PENTAHYDRATE) Powder for concentrate for solution for infusion; Regimen #1	UNK; Unknown	Complicated intra-abdominal infection (Abdominal infection)	MAY-2025 / MAY-2025; Unknown