

Supplementary Table II. Approval, use, and market outlook of cefepime–enmetazobactam (CPM–EMT) in the US, UK/EU, and India

Region	Approval date and indications	Utilisation/stewardship	Sales and forecast
US	FDA approved on Feb, 2024 for cUTI, pyelonephritis	Early inclusion in HF reviews and AMSP ⁴⁷	5-year GAIN Act exclusivity, strong market growth projected ^a
UK and EU	EMA approved in Mar 2024 for cUTI, HAP/VAP, bacteraemia	High (>96%) <i>in vitro</i> susceptibility among Enterobacterales in UK/EU isolates supports formulary uptake ¹⁷	Commercial rollout led by AdvanzPharma in 2024 ^b
India	Orchid Pharma and Cipla launched on June, 2024 for cUTI, HAP, VAP	Positioned as a carbapenem-sparing option in tertiary-care hospitals amid high <i>ESBL</i> prevalence ²⁸	Strong early adoption projected via Cipla's national distribution network ⁵¹

US, United States; UK, United Kingdom; EU, European Union; cUTI, complicated urinary tract infection; HAP, hospital-acquired pneumonia; VAP, ventilator-associated pneumonia; GAIN Act, generating antibiotic incentives now act (US law providing exclusivity to new antimicrobials); HF, hospital formulary; IRP, International recognition procedure (MHRA fast-track approval route); *ESBL*, extended-spectrum β -lactamase (resistance mechanism among Enterobacterales); AMSP, antimicrobial stewardship programme