Recommendations of the SEC (Antimicrobial & Antiviral) made in its 04th/25 meeting held on 08.04.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	BABE/CT05/FF/2024/45078 Artesunate 200 mg, Sulfamethoxypyrazine 500 mg and Pyrimethamine 25 mg Tablets	M/s Ajanta Pharma Limited	The firm presented the BA/BE study Protocol No. BIOS/2024/101, Version No. 01, Protocol Date- 13-AUG-2024 for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only, subject to condition that all the participating subjects should be screened for sulfa drug allergy test before enrolling into the study. Accordingly, the firm should submit revised protocol to CDSCO for review.
2.	BABE/CT05/FF/2024/45721 Bedaquiline and Pretomanid tablets 200 mg/200 mg	M/s Aizant Drug Research Solutions Private Limited	The firm presented the Protocol No. BEPR-TBZ-1002, Version No: 01, Date: 06 Sep 2024 for BA/BE study for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only as presented by the firm with a condition to include safety and toxicity in the objective of the study. Accordingly, the firm should submit revised protocol to CDSCO for review.
3.	BABE/CT05/FF/2024/45672 Bedaquiline and Pretomanid tablets 200mg/200mg	M/s Aizant Drug Research Solutions Private Limited	The firm presented the Protocol No. BEPR-TBZ-1001, Version No: 01, Date: 06 Sep 2024 for BA/BE study for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only as presented by the firm with a condition to include safety and toxicity in the objective of the study. Accordingly, the firm should submit revised protocol to CDSCO for review.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
4.	SND/CT/21/000028 Remdesivir Injection 100mg/20ml [5mg/ml]	M/s JSS Medical Research Asia Pacific Private Limited	The firm did not turn up for presentation.
FDC Division			
5.	FDC/MA/24/000159 Nitrofurantoin 100 (mg) FlavoxateHydrochloride 200 (mg) Tablet	M/s Unicure India Ltd	Under Discussion.
New Drugs Division			
6.	F. No. ND/CT/24/000058 Cefepime 2gm and Enmetazobactam 500 mg Dry Powder for Injection	M/s Orchid Pharma Limited	In light of earlier SEC recommendation dated 24.10.2024 wherein firm was recommended to conduct Phase IV CT study by including the clause under inclusion criteria that '*During screening, Rapid test for ESBL producing organism must be done and only positive patients should be enrolled, in addition to the culture sample'*. Firm re-deliberated their proposal before the committee for the amendment of above inclusion criteria. After detailed deliberation, the committee agreed for the amendment of said inclusion criteria as proposed by the firm, which is detail below: **a) Screen and Enrol Based on Clinical Suspicion:** Initially enrol all patients with clinically suspected Gram-negative infections, initiate empirical treatment (Cefepime 2 gram and Emmetazobactum 500 mg Dry Powder for Injection) as per study protocol. **b) Confirm ESBL Status via Rapid kit and Culture:** Perform both

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Rapid and standard culture sensitivity testing to confirm ESBL production. Based on these results, discontinue study treatment and initiate alternative antibiotics for non-ESBL producing isolates. For ESBL-positive patients, continue study treatment as per the study protocol. Accordingly, the firm should submit the revised Phase-IV CT protocol to the CDSCO.