Recommendations of the SEC (Antimicrobial & Antiviral) made in its 3rd meeting held on 06.03.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/37/24 Online Submission (37497) Aztreonam and Avibactam (1.5 g/0.5 g) Powder for Concentrate for Solution for Infusion	M/s Pfizer Limited	The firm presented protocol amendment 1 dated 02 December 2024 protocol no. C3601010. After detailed delibration, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/80/22 Online Submission (37503) Avibactam+Aztreonam (PF-06947387)	M/s Pfizer Limited	The firm presented protocol amendment 4 dated 02 December 2024 and Increase the number of subjects in India 12 to 15 protocol no. C3601008. After detailed delibration, the committee recommended for approval of protocol amendment and Increase the number of subjects in India (12 to 15) as presented by the firm.
3.	E-Mail Dated: Tue, 04 Feb 2025 17:55:10 Six- Month Regimen of High-Dose Rifampicin, High-Dose Isoniazid, Linezolid, and Pyrazinamide versus a Standard Nine-M	M/s B J Govt. Medical College Clinical Trial Unit	The firm presented phase II clinical study protocol titled "A5384: A Phase II, Randomized, Open-Label Trial of a Six-Month Regimen of High-Dose Rifampicin, High-Dose Isoniazid, Linezolid and Pyrazinamide versus a Standard Nine-Month Regimen for the Treatment of Adults and Adolescents with Tuberculosis Meningitis (IMAGINE TBM)". After detailed delibration, the committee opined that research may be allowed subject to the condition that scientific justification with respect to high dose of rifampicin shall be submitted to SCRP.
BA/BE Division			
4.	BABE/CT05/FF/2024 /45078 Artesunate 200 mg, Sulfamethoxypyrazine 500 mg and Pyrimethamine 25 mg	M/s Ajanta Pharma Limited	Firm did not turn up for the presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Tablets		
5.	BABE/CT05/FF/2024 /45721 Bedaquiline and Pretomanid tablets 200 mg/200 mg	M/s Aizant Drug Research Solutions Private Limited	Firm did not turn up for the presentation.
6.	BABE/CT05/FF/2024 /45672 Bedaquiline and Pretomanid tablets 200mg/200mg	M/s Aizant Drug Research Solutions Private Limited	Firm did not turn up for the presentation.
SND Division			
7.	SND/MA/24/000188 Polymyxin B 10,00,000 IU/vial	M/s.Venus Remedies Limited	Firm did not turn up for the presentation.
8.	SND/CT/21/000028 Remdesivir Injection 100mg/20ml [5mg/ml]	M/s JSS Medical Research Asia Pacific Private Limited	Firm did not turn up for the presentation.
9.	SND/MA/21/000548 Linezolid Sustained Release Tablets 1200mg	M/s Akums Drugs & Pharmaceuticals Limited	In light of earlier SEC recommendation dated 26.11.2024 and 27.11.2024, the firm presented the proposal for grant of permission to conduct Post Marketing Surveillance study of the Linezolid Sustained Release Tablets 1200 mg along with revised PMS protocol (Protocol No. VRL-CT-24-006, Version: 2.0, Dated: 08.01.2025) before the committee. After detailed delibration, the Committee recommended for grant of approval for PMS Study as per the revised protocol presented by the Firm.
New Drugs Division			
10.	ND/CT/24/000004 Tafenoquine Tablets 50mg and 150mg	M/s Glaxosmithkline Pharmaceuticals Limited	The firm presented the proposal for amendment in Phase-III CT protocol of Tafenoquine Tablets 50mg and 150mg (Amended Protocol no. 208550, Version 02 dated 25.06.2024), before the committee. After detailed delibration, the committee did not agree to add the iSRC for review of planned interim analysis of the

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			pediatric population in lieu of IDMC as recommended in the earlier SEC (Antimicrobial & Antiviral) meeting dated 10.04.2024. Thus, the condition mentioned in the permission to carry out Phase-III CT dated 15.07.2024 i.e."Firm should submit IDMC recommendations along with interim analysis report of pediatric participants 12 to 18 year of age as per the protocol to CDSCO for further review by the committee for extension of the study" remain unchanged. The committee agreed for the amendment of protocol for the other changes as proposed by the firm. Accordingly, the firm should submit the revised Phase-III CT protocol to the CDSCO.