Recommendations of the SEC (Antimicrobial & Antiviral) made in its 09th/25 meeting held on 19.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/70/25 Online Submission (49835) Bemnifosbuvir + Ruzasvir	M/s IQVIA RDS (India) Private Limited	The firm presented Phase III clinical trial study Protocol No. AT-01B-008 version No. 2, amendment 1 dated 01-Apr-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.
2.	CT/170/22 Online Submission (40167) Ibrexafungerp Tablet	M/s PSI CRO Pharma Pvt Ltd	The firm presented protocol amendment 3 dated 04 August 2023 & protocol amendment 4 dated 12 August 2024 protocol no. SCY-078-302. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/110/25 Online Submission (51071) Combination of Pocapavir Capsules 160 mg/80 mg+ Imocitrelvir Capsules 160 mg/80 mg	M/s Veeda Clinical Research Limited	The firm presented Phase III clinical trial study Protocol No. 23-VIN-0506 version No. 01dated 14-Jun-2025. After detailed deliberation, the committee opined that the firm shall submit the following for further review by committee in presence of experts from ICMR and Vaccine experts (Govt of India). 1. Safety and efficacy data of this IMP, already used for 12 patients utilised for compassionate ground. 2. Data regarding the approval of use of the IMP for compassionate ground in those 12 patients. 3. Details of all test performed for primary immunodeficiency and iVDPV.
SND Division			
4.	SND/MA/21/000223 Liposomal Amphotericin B Injection 50 mg/vial (Lyophilized)	M/s. Gufic Biosciences Limited	The firm presented the proposal for grant of permission to conduct Active Post Marketing Surveillance (PMS) Study vide protocol No. GB_LAB_001_21, Version 02 dated 25.02.2025 before the committee. After detailed deliberation, the committee recommended to submit the revised Active PMS Study protocol with following changes to CDSCO.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			1) Addition of 'Case definition' in Study Inclusion Criteria 2) Terminology of 'Visit' to be changed as 'Monitoring'. Accordingly, the firm should submit the revised Active PMS Study protocol to CDSCO within 15 days
5.	SND/MA/22/000210 Meropenem Injection IP 125 mg	M/s. Aristo Pharmaceuticals Private Limited	The firm did not turn up for the presentation.
New Drugs Division			
6.	ND/CT/24/000032 Colloidal Nano Silver Gel (SilverSole)	M/s Biosphere Clinical Research Private Limited	In light of the earlier recommendation of Dated 25.07.2024, firm presented phase I Clinical Trial study to evaluate the safety and pharmacokinetics of drug product Colloidal Nano Silver Gel (SilverSole) (Protocol No.: BCR-VIR-003 and date of report 12.05.2025) in Healthy Adult Female subject before the committee. After detailed deliberation the committee observed that the complete details with respect to the pharmacokinetics study are not reflected in power point presentation presented by firm. Further, the committee noted that Colloidal Nano Silver vaginal gel is not yet approved in India and other countries and opined that committee needs to review complete protocol, report and toxicity data for further necessary action.