Recommendations of the SEC (Antimicrobial & Antiviral) made in its 08th/25 meeting held on 15.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/CT/25/000050 Povidone Iodine Alcoholic Prep 10% w/v (Betadine)	M/s G.S. Pharmbutor Private Ltd	The firm did not turn up for the presentation.
2	SND/MA/22/000119 Clotrimazole Vaginal Film 50 mg	M/s Hetero Healthcare Limited	The firm presented the proposal for grant of permission to conduct Active Post Marketing Surveillance (PMS) Study vide protocol No. HHCL/03-01/25, Version 1.0 dated 25.03.2025 before the committee. After detailed deliberation, the committee recommended for approval to conduct the study as per the protocol presented by the firm.
3	SND/MA/24/000228 Fosfomycin Trometamol BP 3.000 gram Powder Sachet	M/s SRS Pharmaceuticals Pvt. Ltd.	Firm presented Phase III clinical trial report of the Fosfomycin (Trometamol) Powder 3 gm in patients for proposed indication before the committee. After detailed deliberation, the committee desired to submit the detailed efficacy results in correlation with microbial culture testing including the Fosfomycin resistant microbes performed in Chronic Bacterial Prostatitis (CBP) Positive patients to CDSCO for further review by the committee.
New Drugs Division			
4	GCT/9/2024-eoffice Six- Month Regimen of High - Dose Rifampicin, Hig- Dose Isoniazid, Linezolid, and Pyrazinamide versus a Standard Nine-Month Regimen for the Treatment of Adults and Adolescents with	M/s B J Govt. Medical College Clinical Trial Unit	Under Discussion.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Tuberculosis Meningitis (IMAGINE TBM)		
FDC Division			
5	FDC/CT/22/000080 Amoxycillin Trihydrate IP Eq. to Amoxycillin 600 mg + Potassium Clavulanate diluted IP Eq. to Clavulanic acid 42.9 mg per 5 ml Powder for oral suspension	M/s Sun Pharmaceutical Industries Limited	In light of earlier SEC recommendation dated 22.03.2023 and as per condition of Form CT-23 dated 30.09.2022, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.
6	FDC/MA/24/000205 Amoxycillin Trihydrate IP eq. to Amoxycillin 600 mg + Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9 mg uncoated orodispersible tablet	M/s Malik Life Sciences	In light of earlier SEC recommendation dated 26.11.2024, the firm presented the proposal along with Phase III CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III CT study with the proposed FDC. Accordingly, the firm should submit Phase III CT report to CDSCO for further review by the committee.
7	FDC/MA/24/000264 (A) Piperacillin and Tazobactam Injection I.P. 4.5 gm Each bag contains: Piperacillin Sodium IP (Sterile) eq. to piperacillin 4 gm + Tazobactam Sodium (Sterile) IP eq. to Tazobactam 500 mg and (B) Sodium Chloride Injection IP 0.9 % w/v 100 ml in dual chamber Bag	M/s Gufic Biosciences Limited	In light of earlier SEC recommendation dated 14.05.2025, the firm presented the proposal along with request for BE, Phase III CT waiver and justification of strength of diluent Sodium Chloride before the committee. The committee noted that the said FDC with Sodium Chloride Injection in dual chamber bag is already approved by USFDA. After detailed deliberation, the committee considered the request for BE and Phase III CT waiver and recommended for grant of permission for manufacturing and marketing with the condition to conduct the Phase IV clinical trial. Accordingly, the firm should submit

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.
8	FDC/CT/25/000059 Aztreonam 1.5 gm + Avibactam 0.5 gm Powder for concentrate for solution for infusion	M/s Pfizer Limited	The firm did not turn up for presentation.