Recommendations of the SEC (Antimicrobial & Antiviral) made in its 10th/24 meeting held on 24.10.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT/24/000058 Cefepime 2 gram and Emmetazobactum 500mg Dry Powder for Injection	M/s Orchid Pharma Limited	Firm presented the proposal for grant of permission to conduct phase IV clinical trial with new drug Cefepime 2g and Enmetazobactam 500 mg dry powder for injection before the committee. After detailed deliberation, the committee recommended the conduct of Phase IV study including the following clause under inclusion criteria: 1. During screening, Rapid test for ESBL producing organism must be done and only positive patients should be enrolled, in addition to the culture sample. 2. The study site should ensure administration of test dose. The following should be included in exclusion criteria: 1. Patients with major cardiovascular disorders including uncontrolled hypertension must be excluded. 2. Patients with symptoms suggestive of Colitis. 3. Patients with hypersensitivity to Cephalosporins. The firm should submit revised protocol to CDSCO.
FDC Division			
2.	FDC/MA/24/000214 Ofloxacin IP 200 mg + Metronidazole Benzoate IP eq. to metronidazole ER 500 mg film coated tablets	M/s Unique Pharmaceutical Laboratories	The firm presented the proposal along with BE study protocol and justification for CT waiver before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, the firm should submit BE study report to CDSCO for further review by the committee. Further, decision on the Phase III clinical trial may be taken after review of BE study results.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
3.	SND/MA/23/000123 Clarithromycin Extended Release Tablets 1000mg	M/s. Abbott Private Limited	In light of earlier SEC recommendation dated 9/5/2024, the firm presented the justification for Phase III CT waiver along with BE data before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Clarithromycin extended release tablets 1000mg subject to condition that the firm shall conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV CT protocol within 3 months from the date of approval to CDSCO for further review by the committee.