Recommendations of the SEC (Antimicrobial & Antiviral) made in its 08th/24 meeting held on 22.08.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/159/23 Online Submission (33759) Cefepime + Zidebactam	M/s. Wockhardt Limited	The firm presented the protocol amendment 1, version 2.0 dated 27 June 2024 protocol No. W-5222-202. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/154/23 Online Submission (34151) Sisunatovir (PF-07923568) Tablet	M/s. Pfizer Limited	The firm presented the protocol amendment 1 dated 30 April 2024 protocol No. C5241007. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/37/24 Online Submission (42311) Avibactam 0.5 g + Aztreonam 1.5 g Powder for Concentrate for Solution for Infusion	M/s. Pfizer Limited	The proposal may be deliberated in presence of paediatric infectious disease expert and one infectious disease expert.
4.	CT/80/22 Online Submission (34238) Avibactam + Aztreonam (PF-06947387)	M/s. Pfizer Limited	The firm presented the protocol amendment 3 dated 10 June 2024 protocol No. C3601008. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
5.	SND/MA/24/000076 Tioconazole vaginal film 300 mg (Additional dosage form)	M/s. Hetero Healthcare Limited	Firm presented the proposal for manufacturing and marketing of Ticonazole Vaginal Film 300 mg along with Phase III protocol (Protocol No. HHCL/01-01/24 version 1.0 dated 18/01/2024) before the committee. The committee noted that Ticonazole Vaginal film 300mg is not approved in anywhere in the world. However, Ticonazole vaginal gel 65mg/gm is approved in India on dated 22.03.2011. The committee noted that the justification

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			for using Reference drug - Canesten V6 (Clotrimazole) vaginal tablet 100 mg not adequate when the dosage form of Ticonazole are available. Also the applied dose is 5 fold higher than the approved dose (Ticonazole vaginal gel 65 mg / gm). Committee urged that, such higher dose should be supported by preclinical data and vaginal toxicity data. After detail deliberation, the committee opined that the firm should submit adequate rational/ justification for the development of proposed dosage form in such high strength along with release pattern data of the proposed formulation, adequate toxicity data, anticipated side effects and supportive clinical evidence of proposed dosage form to CDSCO for further review by the committee.
FDC Division			
6.	FDC/IMP/24/000001 Aztreonam 1.5gm + Avibactam 0.5gm Powder for concentrate for solution for infusion	M/s. Pfizer Limited	The firm presented the proposal before the committee. The firm informed that the said FDC is already approved in Belgium, Bulgaria, Czechia, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Hungary, Malta, Netherlands, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Finland, Sweden and the United Kingdom (Northern Ireland). Further, firm presented Phase III CT report including the Indian subpopulation (27 subjects at 7 sites) as global clinical trial. After detailed deliberation, the committee recommended for grant of permission to import and market of the FDC with the condition to conduct the Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			CDSCO within 3 months of approval of the FDC for review by the committee.