Recommendations of the SEC (Antimicrobial & Antiviral) made in its 06th/24 meeting held on 20.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/39/21 Online Submission (32345) Cipargamin (KAE609)	M/s. Novartis	The firm presented safety & efficacy data with DMC report in compliance to condition No. 4 of CT NOC for protocol No. CKAE609B12201. After detailed deliberation, the committee accepted the safety & efficacy data with DMC report in compliance to condition No. 4 of CT NOC as presented by the firm.
SND Division			
2.	SND/MA/23/000046 Sodium Fusidate Tablets 250 mg	M/s. Windlas Biotech Limited	In light of earlier SEC recommendations dated 26.07.2023, the firm presented bioequivalence study report along with justification for waiver of Phase-III clinical trial before the committee. The firm informed that the Sodium Fusidate tablets 250mg is not yet approved in India. However, the applied product is already approved in UK, Australia, New Zealand and other European countries such as Austria, Denmark, France, Spain, Greece, Ireland, Netherlands & Portugal. After detailed deliberation, the committee noted that the proposed formulation is very old and approved in Europe since 1987- and first-time oral formulation is introduced in India. Further, proposed oral tablet is not act a stand-alone drug and used in combination of other antimicrobial drugs. Therefore, the committee opined that the firm should submit clinical efficacy and safety data on Indian or Caucasian population to CDSCO for further review by the committee.
3.	SND/MA/23/000168 Povidone Iodine Alcoholic Preparation	M/s G.S. Pharmbutor	The firm presented the proposal for grant of permission to manufacture and marketing of Povidone Iodine Alcoholic preparation 10% w/v along with

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	10% w/v		justification for waiver of Phase-III clinical trial before the committee. The firm informed that similar topical formulation Povidone Iodine ointment USP 10% is approved in India. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Povidone Iodine Alcoholic preparation 10% w/v with Ethanol 30% v/v for the disinfection of the skin prior to Invasion surgical procedure, proposed indication with clinical trial waiver subject to condition that the firm should conduct Phase-IV clinical trial. In addition to above, the firm should fulfill the requirement of CMC data. Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from the date of approval of drug for further review by the committee.
4.	SND/MA/22/000119 Clotrimazole Vaginal Film 50mg	M/s Hetero Healthcare Private Limited	In light of earlier SEC recommendations dated 28.07.2022, the firm presented the Phase-III clinical study report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Clotrimazole vaginal film 50 mg subject to condition that the firm should conduct active PMS study. In addition to above, the firm should fulfill the requirement of CMC data. Accordingly, the firm should submit active PMS study protocol to CDSCO within 03 months from the date of approval of drug for further review by the committee.
New Drugs Division			
5.	ND/CT/24/000010 Inosine Pranobex 500mg and 1000mg	M/s. Themis Medicare Limited	The firm presented the Phase IV CT protocol before the committee. After detailed deliberation the committee

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			recommended for grant of permission to conduct the phase IV clinical trial as per the protocol presented.
6.	ND/CT/24/000033 Plazomicin Injection 500 mg/10 ml	M/s. Cipla Ltd.	The firm presented the Phase IV CT protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the Phase IV clinical trial with new drug Plazomicin injection 500 mg/10 ml as per the protocol presented.
7.	12-01/24-DC (Pt-66) Pyrantel Pamoate USP	ICMR-VCRC, Puducherry	The applicant presented the proposal before the committee. After detailed deliberation the committee recommended there may no objection for conduct of the study as academic clinical trial.
FDC Division			
8.	FDC/MA/20/000150 Zic Citrate Trihydrate eq. to Zinc IP 10mg + Ascorbic acid IP 1000mg effervescent tablets	M/s. Kusum Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 27.09.2022, the firm presented the proposal along with Active PMS report before the committee. After detailed deliberation, the committee noted and agreed the results of the report.