Recommendations of the SEC (Antimicrobial & Antiviral) made in its 122nd meeting held on 31.01.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/18-DC (Pt -337) Albendazole associated diahorrea	PvPI, IPC	The recommendation of the SRP-PvPI, IPC was placed before the committee. After detailed deliberation, the committee recommended that CDSCO should request the State Drugs Controllers to direct the manufacturers of the drug to include Albendazole associated diarrhoea in the PIL of the marketed products.
2.	ND/MA/22/000116 Icaridin spray 20% w/v	M/s. Care Now Medicals Pvt. Ltd.	In light of earlier SEC recommendation dated 29.11.2023, the firm presented detailed published literature on mechanism of action as mosquito repellent along with efficacy and safety of drug Icaridin. The committee noted that drug Icaridin is approved in USA since 2001 and Canada since 2012. After detailed deliberation, the committee recommended for the grant of permission to manufacture and market the drug Icaridin spray 20% w/v spray.
3.	12-73/13-DC Bedaquiline Tablets 20mg & 100mg	M/s Johnson & Johnson Pvt. Ltd.	In light of earlier SEC recommendation dated 20.10.2022, the firm presented their proposal along with updated prescribing information before the committee. After detailed deliberation, the committee recommended that, the firm should submit the additional data along with international data if any to CDSCO for further review by the committee.
4.	12-01/20-DC (Pt - 264) Isavuconazole capsule 100mg & 200mg powder for concentrate for solution for infusion	M/s Pfizer	The firm was granted import and marketing permission of Isavuconazole Capsule 100mg & 200mg powder for concentrate for solution for infusion on 14.02.2020 and 11.03.2020 respectively subject to condition that "Active PMS study should be conducted on at least 50 patients of confirmed cases of Invasive Aspergillosis and 20 patients of confirmed cases of Invasive Mucormycosis". The firm has submitted PMS study protocol and the same was

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			deliberated in SEC (Antimicrobial & Antiviral) meeting held on 07.08.2020. Accordingly, the permission to conduct the PMS study was issued by CDSCO on 24.08.2020. The firm presented the PMS study report before the committee. After detailed deliberation, the committee noted that the total number of deaths during the study was 41 (58.6%), which were majorly COVID-19 related. No treatment related adverse drug reactions (ADR), serious ADR or ADRs leading to treatment discontinuation were reported. Overall, Isavuconazole was safe and well tolerated in this study.
SND Division			
5.	SND/MA/22/000358 Cefixime Oral Suspension IP 200 mg/5ml	M/s Alkem Laboratories	The firm presented the proposal for manufacturing and marketing permission of Cefixime Oral Suspension IP 200mg/ml indicated in the treatment of pediatric patients 6 month of age or older with the following infection when caused by susceptible isolates of designated bacteria: 1. Otitis media caused by Haemophilus influenza, Moraxella catarrhalis, and Streptococcus pyogens. 2. Pharyngitis and tonsillitis caused by Streptococcus pyogens. 3. Acute exacerbation of chronic bronchitis caused by Streptococcus pneumoniae and Haemophilus influenza. 4. Uncomplicated Urinary Tract infections caused by Escherichia coli and Proteus mirabilis . 5. For the treatment of enteric (typhoid) fever. The firm presented the rationale for Bio equivalence and clinical trial waiver. After detailed deliberation, the committee recommended that, as the firm did not have the safety data on Indian population, the firm is required to conduct the Phase III clinical trial and submit the clinical trial protocol and relevant documents for

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			further deliberation by the SEC committee.
6.	SND/IMP/21/000062 Klercide low residue quat (quaternary ammonium-based disinfectant liquid)	M/s. Ecolab Food safety and hygiene solutions Pvt. Ltd.	The firm presented their proposal alongwith some antimicrobial study of their product and approval status of the product in other countries before the committee. After detailed deliberation, the committee recommended that the firm should submit comparative data of the applied product with already approved disinfectant by CDSCO for further review by the committee.
7.	SND/IMP/21/000064 Klercide low residue peroxide wipes (Hydrogen peroxide based disinfectant wipes)	M/s. Ecolab Food safety and hygiene solutions Pvt. Ltd.	The firm presented their proposal alongwith some antimicrobial study of their product and approval status of the product in other countries before the committee. After detailed deliberation, the committee recommended that the firm should submit comparative data of the applied product with already approved disinfectant by CDSCO for further review by the committee.
8.	SND/MA/22/000220 Feracrylum 1% mouth gargle	M/s. Themis Medicare	In light of earlier recommendation of SEC held on 27.09.2022 and 29.09.2022 the firm presented their proposal of manufacture and marketing of Feracrylum 1% mouth-gargle for the proposed indication that "Oral Mucositis" with request to local clinical trial waiver. After detailed deliberation, the committee did not concede the request for local clinical trial waiver and recommended to conduct Phase III clinical trial. Accordingly, the firm was requested to submit the Phase III clinical trial protocol to CDSCO for further review by the committee. Subsequently on 31.01.2023, the firm presented their proposal for manufacture and market the above drug for the new indication that "antiseptic mouth wash" with request to local clinical trial waiver before the committee. After detailed deliberation, the committee did not consider the request for local

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			clinical trial waiver. In view of the above, the committee recommended that the firm should submit Phase III clinical trial protocol for proposed indication that "antiseptic mouth wash" to CDSCO for further review by the committee.
9.	SND/MA/22/000352 Pretomanid Tablets 200 mg	M/s. Mylan Laboratories	The firm presented their proposal for manufacture and marketing of the drug product Pretomanid Tablets 200mg for the following indication before the committee; "As part of a combination regimen with Bedaquiline and Linezolid, for treatment of MDR-TB or RR-TB in patients ≥14 years of age who have no previous exposure (defined as >1 month) to Bedaquiline, Pretomanid, or Linezolid, with Moxifloxacin in the absence of baseline resistance to Fluoroquinolones or without Moxifloxacin if resistance to Fluoroquinolones is present (pre-XDR-TB)". After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug Pretomanid Tablets 200mg for the proposed indication with the same condition of the initial approval of the drug.
FDC Division			
10.	FDC/MA/22/000159 Sodium Ascorbate eq. to Ascorbate acid IP 400mg 120mg + L-Lysine Hydrochloride USP 7.49mg eq. to L-Lysine USP +Ascorbic acid 50mg + Ascorbyl Palmitate 6mg Chewable tablet	M/s. Zuventus Healthcare Ltd.	The firm didn't turn up for presentation.
11.	FDC/MA/21/000232 Tinidazole 100mg +Norfloxacin 100mg suspension	M/s. Rivpra Formulation Pvt. Ltd.	In light of earlier SEC recommendation dated 25.05.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee reiterated its earlier recommendation.

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GCT Division			
12.	CT/51/18 Online Submission (19520) Aztreonam-Avibactam (ATM-AVI)	M/s Pfizer	The firm has withdrawn the application.