Recommendations of the SEC (Antimicrobial & Antiviral) made in its 01st/25 meeting held on 21.01.25. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/159/23 Online Submission (36620) Cefepime + Zidebactam	M/s Wockhardt Limited	The firm presented protocol amendment 2, version 3.0 dated 19 Dec 2024 protocol No.: W-5222-202. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/93/23 Online Submission (36745) Cefepime + Tazobactam	M/s Wockhardt Limited	The firm presented protocol amendment 1, version 2.0 dated 11 Dec 2024 protocol No: W-4282-303. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
3.	BIO/CT21/FF/2024/45727 Dengue Monoclonal Antibody (Recombinant) 25 mg/mL (240 mg/9.6 mL)	M/s Serum Institute of India Pvt. Ltd.	The firm presented the proposal to manufacture and market Dengue Monoclonal Antibody (Recombinant) 25 mg/mL (240 mg/9.6 mL) for the treatment of Dengue in adults (≥ 18 years). The firm has presented justification for considering the approval under accelerated approval process as per Second Schedule of NDCT Rules along with clinical study results of Phase I study conducted in Australia and Phase II study conducted in India. Further, firm has claimed that there is an unmet medical need in the country and no approved therapy is available. Firm has committed to conduct PMS study in larger population. After detailed deliberation, the committee did not consider the firm's proposal to manufacture and market Dengue Monoclonal Antibody (Recombinant) 25 mg/mL (240 mg/9.6 mL) as the safety and efficacy data is available for limited subjects and the therapeutic effect on the severity of disease is not shown in the conducted studies. Further the committee recommended that safety and efficacy data in larger number of patients from Phase III studies shall be

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			submitted before the committee for further deliberation.
BA/BE Division			
4.	BABE/CT05/FF/2024 /45563 Pretomanid, Bedaquiline (as fumarate) and Moxifloxacin Film coated Tablets 200mg/100mg/400mg .	M/s Macleods Pharmaceuticals Ltd.	The firm presented BA/BE study Protocol No. BEQ-3790-PBM(F)-2024 Version No.01 Protocol Date13-FEB-2024 for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study for export purpose as per the protocol presented subject to following addition in the exclusion criteria: - The Volunteers with history of TB infection and TB disease should be excluded. Accordingly, revised protocol should be submitted to CDSCO for approval.
SND Division			
5.	SND/CT/24/000052 VRP-034 (novel formulation of Polymyxin B 750,000 IU)	M/s Veeda Clinical Research Limited	In light of earlier recommendation dated 26.11.2024 & 27.11.2024, the firm presented the revised Phase I Clinical Trial Protocol no. 23-VIN-0367; Version No.: 02 dated 23-Dec-2024 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with following changes in study protocol: 1. Firm should change the formulation of VRP-034 as 5 lakh IU instead of 7.5 lakh IU in the Phase 1 clinical trial protocol. 2. In Single ascending dose (SAD) study, firm is required to start with dose 0.4 mg/kg in Cohort 1, thereafter proceed to Cohort 2 (dose 0.75 mg/kg) and subsequently to Cohort 3 (1.5 mg/kg). Further, Multiple ascending dose study (MAD) cohort will be same. 3. Outcome of each Cohort shall be

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			evaluated by DSMB before moving to the next cohort. Accordingly, the firm shall submit the revised protocol to CDSCO.
6.	SND/MA/22/000015 Povidone Iodine Nasal Solution 0.5% w/v	M/s G.S.Pharmbutor	In light of earlier recommendation dated 26.11.2024 & 27.11.2024, firm presented the published literature for systemic toxicity data included Thyroid function test along with clinical trial report having Protocol no. CT-CE-NS-2022, ver. no. 2.0 dated 29-Aug-2023 before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and market of Povidone Iodine Nasal Solution 0.5% w/v for the applied indication subject to condition that the firm should conduct PMS study. Accordingly, the firm should submit PMS study protocol to CDSCO within 03 months from the date of approval of drug for further review by the committee