Recommendations of the SEC (Antimicrobial & Antiviral) made in its 119th meeting held on 20.10.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-73/13-DC Bedaquiline Tablets 100mg & 20mg	M/s. Johnson & Johnson	The firm presented their proposal along with updated prescribing information before the committee. After detailed deliberation, the committee recommended that the firm should provide details of supportive safety related data available in India & Globally to CDSCO for further review by the committee.
2.	ND/MA/22/000089 Bictegravir, Emtricitabine, TenofovirAlafenamide tablets	M/s. Cipla	In light of earlier SEC recommendation dated 26.07.22, the firm presented their proposal before the committee. After detailed deliberation, the committee reiterated its earlier recommendation dated 26.07.22.
3.	ND/MA/22/000123 Dalbavancin for injection 500mg	M/s. BDR Pharmaceuticals	The firm did not turn up for presentation.
SND Division			
4.	SND/MA/22/000210 Meropenam Injection 125 mg	M/s. Aristo Pharmaceuticals	The firm presented the proposal for manufacturing and marketing of Meropenem Injection 125 mg indicated in children for management for treatment of the following infection caused by single or multiple bacteria sensitive to Meropenem: pneumonia and nosocomial pneumonia, urinary tract infections, intra –abdominal infection, skin and skin structure infections, meningitis septicemia. Meropenem has been proved to be efficacious alone or in combination with other antimicrobial agents in the treatment of polymicrobial infection. After detailed deliberation, the committee recommended for manufacturing and marketing of Meropenem Injection 125 mg for proposed indication. The committee also opined that the firm should also submit the PMS data generated in children with Meropenem Injections.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	SND/MA/21/000060 Liposomal Amphotericin B Injection 50 mg/ml (Lyophilized)	M/s. Mylan Laboratories	The firm presented proposal for realignment of the indication for Liposomal Amphotericin B Injection 50 mg/ml (Lyophilized) as per approved indication in country of origin. After detailed deliberation, the committee recommended for grant for realignment of the indication for Liposomal Amphotericin B Injection 50 mg/ml (Lyophilized) as follows; 1.) For treatment of systemic mycotic infection. 2) Fever of unknown origin (FUO) in patients with neutropenia. 3) For the treatment of visceral leshmaniasis.
FDC Division			
6.	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 acid50mg +Ascorbyl Palmitate6mgChewable tablet	M/s. Zuventus Healthcare Ltd.	The firm did not turn up for presentation.
Medical Device Division			
7.	IMP/MD/2021/42818 High-level disinfectant for thermosensitive instruments and endoscopy equipment (ANIOXYDE 1000 LD)	M/s. Ecolab Food Safety and Hygiene Solutions Private Limited	The firm did not turn up for presentation.
GCT Division			
8.	CT/80/22 Online Submission (33469) Dated 10/08/22	M/s. Pfizer	The proposal of Phase 2A clinical trial vide protocol no. C3601008 was deliberated before the SEC committee. After detailed deliberation, the committee recommended that the firm should be

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	Aztreonam – Avibactamm + Metronidazole		asked to submit the following for further re-deliberation before the committee: 1. Interim analysis data of two referred ongoing clinical studies in Adults population. 2. Current antibiotics resistance data. 3.Detailed justification/rationale of proposed combination product.