Recommendations of the SEC (Antimicrobial & Antiviral) made in its 120th meeting held on 29.11.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000116 Icaridin 20% W/v spray (Mosquito repellent)	M/s. Care Now Medicals	The firm presented their proposal to import and market the drug Icaridine 20% w/v as mosquito repellent before the committee. After detailed deliberation, the committee opined that the firm should provide the details of published literatures on exact mechanism of action of drug which can substantiate the anti repellent property of the product. Accordingly, the firm should submit the details of published literature on mechanism of action of the product for further review by the committee.
2.	ND/MA/22/000123 Dalbavancin for injection 500 mg	M/s. BDR Pharmaceuticals	The firm did not turn up for presentation.
3.	ND/MA/21/000200 Squaric Acid 1.745mg/ml (AMSAA) spray	M/s. Vital Therapeutics & Formulations Pvt. Ltd.	In light of earlier SEC recommendation dated 23.02.2022, the firm made presentation on safety and efficacy of the product before the committee. After detailed deliberation, the committee opined that the firm should conduct sub-acute toxicological study for 30 days. Accordingly, the firm should submit the results of sub-acute toxicological study for further review by the committee.
4.	ND/MA/21/000201 Squaric Acid 0.748mg/ml (SASAA) Fog	M/s. Vital Therapeutics & Formulations Pvt. Ltd.	In light of earlier SEC recommendation dated 23.02.2022, the firm made presentation on safety and efficacy of the product before the committee. After detailed deliberation, the committee opined that the firm should conduct sub-acute toxicological study for 30 days. Accordingly, the firm should submit the results of sub-acute toxicological study for further review by the committee.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
5.	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 did not turn up for presentation.
6.	FDC/MA/21/000232 Tinidazole 100mg + Norfloxacin 100mg suspension	M/s. Rivpra Formulation Pvt. Ltd	The firm did not turn up for presentation.
GCT Division			
7.	CT/23/18 Online Submission (19989) Aztreonam-Avibactam	M/s. Pfizer	The firm presented the proposed amendment to the REVISIT study protocol no. C3601002, amendment 2 dated 18-May-2022 before the committee. After detailed deliberation, the committee recommended for the approval of the proposed study protocol amendment with condition that there is no increase in the number of subjects compared with earlier approved number from the country owing to the proposed amendment.
8.	CT/163/21 Online Submission (20491) AT-752	M/s. PPD	The firm presented the proposed amendment in the study protocol no. AT-02A-002, amendment 1, dated 29-Jul-2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed study protocol amendment.
New Drug Division			
9.	ND/MA/19/000040 Delafloxacin 450mg	M/s. Synokem	In light of earlier SEC recommendation dated 30.10.2019, the firm presented their revised protocol no. CRPL/CT/19/08, version no. 01 dated 06.11.2019 before the committee. After detailed deliberation, the committee recommended for conduct of Phase III clinical trial for Delafloxacin tablets 450 mg with revised protocol.