Recommendations of the SEC (Antimicrobial & Antiviral) made in its 104th meetingheld on 23.09.2021 & 24-09-2021at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/18/000015 Rifapentine and Isoniazid	M/s Sanofi-synthelab India Private limited	The firm presented their proposal of Observational Study protocol before the committee. The committee noted that the firm was granted import permission dated 08.07.2019 with condition that the firm should conduct Phase-IV clinical trial through National TB elimination Programme Division. After detailed deliberation, the committee recommended that the firm should conduct a Phase-IV clinical trial for which protocol should be developed in consultation with the programme experts and submitted to CDSCO for further review by the committee as per the condition of import permission.
2.	ND/MA/18/000032 Tafenoquine tablets 150 mg	M/. GSK Pharmaceutical Limited	In light of SEC recommendation dated 23.06.2021, the firm presented their proposal for local clinical trial waiver with condition that the firm will conduct Phase-IV clinical trial before the committee. After detailed deliberation, the committee opined that justification presented was not adequate considering that currently this testing facility for G6PD deficiencies is limited and reiterated the earlier recommendation that firm should submit Phase III clinical trial along with revised feasibility protocol for further review by the committee.
3.	ND/CT/20/000108 Pretomanid Tab 200 mg	M/s Mylan laboratories.	The firm presented their proposal of amendment in Phase-IV CT protocol before the committee. After detailed deliberation, the committee recommended for approval of protocol amendment as presented during the meeting.
SND Division			
4.	SND/MA/21/000385 Isavuconazole Oral Solution	M/s Macleods Pharma	The firm presented their proposal for Isavuconazole Oral Solution 10mg/ml along with BE study

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	10mg/ml		protocol and clinical trial waiver. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per protocol presented. The committee also opined that requirement of clinical trial may be evaluated after submission of BE study report.
5.	SND/MA/21/000339 Ethambutol Dispersible Tablets 100 mg	M/s Micro Labs	The firm presented their proposal of Ethambutol Dispersible Tablets 100 mg along with BE study report and other supporting data. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Ethambutol Dispersible Tablets 100 mg, indicated for the management of Mycobacterium Tuberculosis.
6.	SND/MA/20/000215 Povidone Iodine Throat Spray 0.45% w/v	M/s. G.S Pharma	In light of earlier SEC recommendation dated 23/12/2020, the firm presented the justification for clinical trial waiver. After detailed deliberation the committee opined that the firm should submit the supportive scientific literature on the effectiveness for the proposed product on commensal microflora of oro-pharyngeal mucosa and safety on long term usage.
7.	Liposomal Amphotericin B Injection 50mg/vial	M/s Biozenta Life Sciences	In light of earlier SEC recommendation, the firm presented the characterization data of Liposomal Amphotericin B injection 50mg/vial (Lyophilized) before the committee. In light of the incidences of mucormycosis cases in current pandemic situation, after detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Liposomal Amphotericin B Injection 50mg per vial subject to the condition that the firm should submit animal PK data in comparison with innovator to CDSCO. Committee also opined that CDSCO

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			may consider for joint inspection of the firm before grant of manufacturing license by SLA.
FDC Division			
8.	FDC/MA/18/000029 Ceftiaxone Sodium 2gm+Sulbactam Sodium 2gm injection	M/s. Aristo Pharmaceuticals	In light of the SEC recommendation dated 25.04.2019, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended that a Phase III Clinical trial is required before grant of permission of this combination. Accordingly, the firm should submit Phase-III Clinical trial protocol for review by the committee.
9.	FDC/CT/20/000071 Lamivudine 300 mg + Doluteravir 50 mg tablets	M/s. Emcure Pharmaceuticals	The firm did not turn up for presentation.
Medical Device Division			
10.	IMP/MD/2021/41329 Detergent Pre-disinfectant for instruments (ANIOSYME X3),Detergent disinfectant foam for surfaces and medical devices (SURFA'SAFE Premium)	M/s Ecolab Food Safety and Hygiene Solutions Private Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of permission for import of the product for cleaning purpose only. The product insert should clearly indicate the usage for pre–disinfection/cleaning of medical device.
11.	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 presented their proposal before the committee. After detailed deliberation, the committee recommended that the firm should submit data to show adequate activity of the product over time in clinical settings.
GCT Division			
12.	CT/41/21-DCGI GCT/PA/2021/12514 Cipargamin(KAE609)	Novartis	In light of earlier recommendation dated 27.07.2021, the firm presented their justification for the waiver of the conditions before the committee. After detailed deliberation, the committee recommended for waiver of conditions 1& 2 of the clinical trial permission.

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