Recommendations of the SEC (Antimicrobial & Antiviral) made in its 105th meeting held on 27.10.2021 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/18 Delamanid	BJ Medical College, Pune	The firm presented the amendment in Clinical Protocol IMPAACT 2005, Version 3.0 dated 11.06.2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment after taking opinion from Central tuberculosis (TB) Division, MoH&FW.
2.	12-43/14-DC (Pt-F-Phase-IV) Dolutagravir-50mg tablets	M/s. Mylan Lab Ltd.	The firm presented the report of Phase IV clinical trial study results of the drug Dolutagravir-50mg tablets before the committee. The committee noted that the firm should continue active surveillance study in 1000 patients and submit the results to CDSCO for further consideration.
3.	12-01/19-DC (Pt-252) HerbalMicrobicide (phytopharmaceutical drug)	M/s. HLL Life care Ltd	The firm presented their proposal of Phase I clinical trial protocol before the committee in light of earlier recommendations dated 24.03.2021 before the committee. The Committee noted that during presentation, the firm stated that the formulation contains crude extracts. After detailed deliberation, the committee opined the following: 1. The firm should submit detailed clarification whether the product/extract is purified as per the requirement of the rules. Accordingly, detailed clarification/justification should be submitted in light of definition of phyto pharmaceuticals in the rules. 2. The firm should submit details of standardization and purification involved in manufacture of the formulation along with supporting documents. 3. The firm should submit all hard and soft copies of the documents for review by phyto experts as per the earlier recommendations dated 24.03.2021. 4. The firm should submit detailed in-

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			vivo study, non-clinical study data conducted with the product. In view of above, committee recommended that the firm should submit above documents/information for further review by the committee
SND Division			
4.	SND/IMP/21/000060 Liposomal Amphotericin B Injection 50 mg/ml (Lyophilized)	M/s. Mylan Pharmaceuticals	The firm presented their proposal for import and marketing of Liposomal Amphotericin B Injection 50 mg/ml for additional indications requesting local clinical trial waiver. After detailed deliberation the committee recommended that the firm should submit the standard published evidences / documentary evidence in support of the serum concentrations of the drug for the proposed additional indications to CDSCO for further review by the committee.
5.	SND/MA/19/000112 Lincomycin HCLSR Tablet 1000 mg	M/s. Wallance	The firm presented the BE study report along with the revised Phase III CT study protocol before the committee for approval. However during presentation, the firm stated that Phase III clinical trial may not be required for the proposed drug product. Hence, marketing authorization may be issued based on the BE study report. After detailed deliberation the committee recommended that the firm should submit application in writing along with detailed justification for CT waiver to consider the matter further.
6.	SND/MA/21/000368 Pidotimod Oral Liquid 400/800mg & Pidotimod Tablets 400/800 mg	M/s. Wockhardt	The firm presented their proposal for manufacturing and marketing of Pidotimod Oral Liquid (Each 7 ml contains) 400/800mg & Pidotimod Tablets 400/800 mg for expansion of indication as indicated for infections of respiratory system in secondary and primary immunodeficiency with alteration in the maturation of the T cells in adults and children. After detailed deliberation, the committee recommended that the firm should submit detailed justification and published data of safety and efficacy of pediatric patients which should be analyzed and presented along with justification for dose

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			rationality. Further, the committee opined that the matter may be examined in the next SEC Antimicrobial meeting along with a pediatrician.
7.	SND/MA/20/000369 Povidine Iodine Alcoholic Solution 3.0% w/v	M/s. G.S Pharmbutor Private Ltd	In light of earlier SEC recommendations, the firm submitted the detailed justification and published data in support of combination of Povidone Iodine and IPA solution vis-à-vis-single ingredients. After detailed deliberation the committee recommended that the firm should submit Phase III clinical trial protocol for review by the committee.
8.	12-85/2015-DC (Pt-Bharat Serum-SND) Liposomal Amphotericin B Injection 50mg/ml (Lyophilized)	M/s. Bharat serum	The firm presented the active PMS study protocol before the committee for approval. After detailed deliberation, the committee recommended for grant of permission for conduct of the active PMS study as per the protocol presented.
FDC Division			
9.	FDC/MA/20/000232 Tinidazole 100mg +Norfloxacin 100mg suspension	M/s. Rivpra Formulation Pvt. Ltd.	The firm did not turn up for presentation.
10.	FDC/MA/20/000150 Zinc Citrate Trihydrate eq. to Zinc 10 mg + Ascorbic Acid USP 1000 mg Effervescent tablet	M/s. Kusum Healthcare	In light of earlier recommendation dated 23.06.2021 & 24.06.2021, the firm presented revised Phase IV CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase IV Clinical trial.