Recommendations of the SEC (Antimicrobial & Antiviral) made in its 112th meeting held on 21.04.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/22-DC (Pt-99) Rifapentine Minocycline, Clarithromycin	M/s. KIMS, Bhubaneshwar	The applicant presented their proposal before the committee. After detailed deliberation, the committee recommended that there may be no objection for conduct of the study as academic clinical trial.
SND Division			
2.	SND/CT/22/000021 Thymosin Alpha 1 for Injection 1.6 mg in sepsis patients	M/s. Gufic Biosciences	The firm presented the Phase III clinical trial study protocol of Thymosin Alpha 1 for injection 1.6 mg in sepsis patient before the committee for approval. After detailed deliberation, the committee recommended that the study design should be revised to a double blind and more government sites should be added in the study. Accordingly, revised Phase III clinical trial study protocol should be submitted for further review by the committee.
FDC Division			
3.	FDC/MA/20/000144 Lamivudine 300 mg + Dolutegravir 50mg tablets	M/s. Emcure Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 23.02.2022, the firm presented their proposal along with the first PSUR data. The committee noted that the FDC is already approved in US, UK, Australia, Japan etc. and is also recommended in WHO 2021 guidelines. After detailed deliberation, the committee recommended for Phase IV clinical trial waiver.