Recommendations of the SEC (Antimicrobial & Antiviral) made in its 132nd meeting held on 29.11.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000160 Rifapentine Dispersible Tablet 150 mg	M/s. Lupin Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Rifapentine Dispersible Tablets 150mg (Additional Dosage Form) for already approved indication along with the Bioequivalence study report before the committee. After detailed deliberation, the committee recommended for approval of Rifapentine Dispersible Tablets 150mg for already approved indication with local clinical trial waiver with condition to conduct a Phase IV Clinical study. Accordingly, the firm should submit Phase IV protocol to CDSCO within 3 months of approval for further evaluation by the committee. However, the firm should fulfill the requirements of CMC data before approval of the product.
FDC Division			
2.	FDC/MA/21/000076 Amoxicillin + Clavulanate Potassium eq. to Clavulanic acid for Oral Suspension USP (600 mg + 42.9 mg) per 5 ml	M/s. Alkem Laboratories Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 10.09.2021, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for following modification in Phase IV clinical trial Protocol: 1. As it is presented as a phase IV clinical study, participants should be enrolled in thousands. 2. Inclusion criteria should be changed for Community-acquired bacterial pneumonia to include microbiology confirmatory tests. 3. Dose of the Potassium Clavulanate should be corrected. 4. North Indian sites should be included to represent pan-Indian representation.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
3.	FDC/MA/22/000019 TenofovirAlafenamide Fumarate IP 25mg + Emtricitabine IP 200mg + Bictegravir Sodium 50mg tablet	M/s. Laurus Labs Ltd.	The firm presented their proposal along with change in warning mentioned in CT-23 from "To be sold by retail on prescription of Gastroenterologist/Hepatologist" to "To be sold by retail on prescription of a RMP only" before the committee. After detailed deliberation, the committee recommended that the warning may be revised to as "To be sold by retail on prescription of a RMP only"
BA/BE Division			
4.	12-09/2023/BA-BE/MISC-33/DC Darunavir and Ritonavir Tablets 120mg/20mg	M/s. Laurus Labs Limited	The firm has withdrawn the application and same was already informed to BA/BE division.