Recommendations of the SEC (Antimicrobial & Antiviral) made in its 02nd/24 meeting held on 22.02.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/23/000098 Cefepime 2g and Enmetazobactam 500mg dry powder for injection	M/s. Orchid Pharma Limited	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Cefepime 2g and Enmetazobactam 500mg dry powder for injection along with protocol for Phase-III clinical trial and request for the waiver of Phase-III clinical trial before the committee. After detailed deliberation, the committee opined that the said combination was presented to be superior to the comparator and this falls under unmet medical need due to increasing cases of Antimicrobial resistance. The committee noted that the said combination is approved by EMA on 25.01.2024. Accordingly, the committee recommended for grant of approval with condition that the firm should conduct Phase IV clinical trial for which the protocol should be submitted within three months of approval of drug for review by the committee.
FDC Division			
2.	FDC/IMP/19/000040 Amoxicillin Trihydrate 759.04mg eq. to Amoxicillin free acid 652.78mg + Potassium Clavulanate 61.48mg eq. to Clavulanic acid 50.41mg per 5ml powder for reconstitution into suspension	M/s. GlaxoSmithKline Pharmaceuticals Ltd.	The firm presented the proposal for update prescribing information for the FDC changes based on the Global Data Sheet (GDS) v25 (dated 10th Feb 2022) and GDS v26 (dated 23rd Feb 2023). After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm.
3.	FDC/MA/23/000205 Copper (II) Nitrate Trihydrate 0.4% +	M/s. Cedrus Bio-Products Pvt. Ltd.	In light of the earlier SEC recommendations dated 23.08.2023 & 31.10.2023, the firm presented antiviral activity report along with scientific

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	Didecyl dimethyl ammonium chloride 80% Solution eq. to Didecyl dimethyl ammonium chloride 4.96% Liquid solution		literature related to the inhalation exposure effects in humans for the proposed FDC. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the FDC.
SND Division			
4.	SND/CT/18/000010 Sodium Fusidate Gel 2%	M/s. Apex Labs Pvt. Ltd.	In light of earlier SEC recommendation dated 20.02.2019. The firm presented the Phase-III clinical trial report of Sodium Fusidate gel 2% w/w before the committee. The firm has informed that as per approved protocol they had planned to conduct Phase-III clinical trial with 312 patients. However, due to Covid-19 pandemic, they had enrolled 186 patients out of which 144 patients completed the study. After detailed deliberation, the committee opined that the firm should complete clinical trial as per the approved protocol and submit the clinical trial report to the CDSCO for further review by the committee.