Recommendations of the SEC (Antimicrobial & Antiviral) made in its 125th meeting held on 25.04.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000159 Dalavancin HCL 500mg injection	M/s. Gufic Biosciences Ltd.	The firm presented the proposal for manufacturing and marketing of Dalbavancin for Injection 500mg along with the results of Phase III clinical trial before the committee. The committee noted that the Dalbavancin for Injection 500mg is approved in countries like U.S.A. and Europe. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Dalbavancin for Injection 500mg subject to the conditions that the firm should conduct Phase IV clinical trial in the country for which protocol should be submitted to CDSCO within three months from the date of approval of the drug for further review by the committee.
2.	ND/MA/23/000039 Tedizolide Phosphate tablet 200 mg	M/s. Synokem Pharmaceutical Ltd.	The firm presented the proposal to conduct bioequivalence study and Phase III Clinical trial for Tedizolid Phosphate Tablets 200mg before the committee. The committee noted that Tedizolid Phosphate Tablets 200mg is already is approved in US, European Union and Canada. After detailed deliberation, the committee recommended for grant of permission to conduct the bioequivalence study and Phase III clinical trial as per the presented protocols.
3.	ND/MA/19/000040 Delafloxacin tablets 450mg	M/s. Synokem	The firm had presented its proposal of BE study in SEC dated 30.10.2019. Wherein, the committee recommended for grant of permission to conduct proposed BE study. Now the firm had revised the BE study protocol no. BIOS/2019/033, version no. 00, dated 20.03.2019, which was already approved by the committee. In this context, the firm presented the revised BE study protocol no. SIC-22-

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			760, version no. 01, dated 03.12.2022, before the committee. After detailed deliberation, the committee recommended to conduct BE study of Delafloxacin Tablets 450mg as per the revised protocol.
4.	ND/MA/22/000089 FDC of Bictegravir 50mg, Emtricitabine 200mg, Tenofoviralafenamide 25mg	M/s. Cipla	In light of earlier recommendations dated 26.07.2022, firm presented its proposal before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of FDC of Bictegravir, Emtricitabine, Tenofoviralafenamide subject to the condition that the firm should conduct Phase IV clinical trial in the country with adequate number of subjects for which protocol should be submitted to CDSCO within three months from the date of approval of the drug for further review by the committee.
SND Division			
5.	SND/MA/21/000190 Liposomal Amphotericin B Injection 50mg/vial (Lyophilized)	M/s. Emcure Pharmaceuticals Ltd.	As per the condition in the manufacturing and marketing permission of Liposomal Amphotericin B Injection 50mg/vial (Lyophilized) granted to the firm, the firm presented the protocol for conduct of active post marketing surveillance study for Liposomal Amphotericin B Injection 50mg/vial (Lyophilized) before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of active post marketing surveillance study as per the protocol presented. The committee also recommended that more clinical trial sites should be included and the site should be geographically distributed in the country.
FDC Division			
6.	FDC/MA/23/000054 Methylcobalamin1500 mcg+Alpha Lipoic acid 100mg+Vitamin D3 IP 8000IU+Calcium Carbonate IP eq. to	M/s. Quality Pharma Products Pvt. Ltd.	The firm did not turn up for presentation.

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	elemental Calcium 225mg+VitaminK2-7 50mcg+Zinc Sulphate USP eq. to elemental Zinc 7.5mg+Magnesium Oxide IP eq. to elemental Magnesium 50mg capsules		
7.	FDC/MA/22/000354 Combikit of Atazanavir 300mg and Ritonavir 100mg Tablet + Emtricitabine 200mg and Tenofovir Alafenamide 10mg Tablet	M/s. Emcure Pharmaceuticals Limited	The firm presented its proposal before the committee along with justification for BE & CT study waiver. The firm presented that FDC of Atazanavir 300mg + Ritonavir 100mg tablets is approved by CDSCO on 04.11.2008 and FDC of Emtricitabine 200mg + Tenofovir Alafenamide 10mg tablet is approved by CDSCO on 10.01.2018. After detailed deliberation, the committee considered the request of firm for BE study and CT study waiver and recommended for grant of permission to manufacture and market the proposed combikitwith the condition that post marketing surveillance study should be conducted. Accordingly, the firm should submit PMS study protocol for proposed Combikit to CDSCO for review by the SEC.
8.	FDC/MA/22/000407 Combikit of Darunavir 800mg and Ritonavir 100mg Tablet + Dolutegravir 50 mg Tablet	M/s. Emcure Pharmaceuticals Limited	The firm presented its proposal before the committee along with justification for BE & CT study waiver. The firm informed that the Phase IV clinical trial result yet to be submitted for Dolutegravir 50 mg Tablet for which permission was already granted by CDSCO on 07.11.2016and FDC of Darunavir 800mg and Ritonavir 100mg Tabletis approved by CDSCO on 02.11.2017. After detailed deliberation, the committee considered the request of the firm for BE study and CT study waiver and recommended that firm should present the Phase IV clinical trial study results of Dolutegravir 50mg tablet. Also, the firm should submit PMS study protocol for proposed Combikit to CDSCO for review by the SEC.