Recommendations of the SEC (Antimicrobial & Antiviral) made in its 05th/25 meeting held on 14.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND-16011(11)/51/2025-eoffice Liposomal Amphotericin B for injection 50mg/vial (Ambiosome)	M/s. Mylan Pharmaceuticals Private Limited	The firm presented the Post Marketing Surveillance study report for the study no. GS-US-131-6403 version no.1.0 dated 23.09.2024 of Liposomal Amphotericin B for Injection 50mg/vial before the committee. After detailed deliberation, the committee recommended to accept the Post Marketing Surveillance study report of Liposomal Amphotericin B for Injection 50mg.
2.	SND/MA/25/000024 Isoniazid Dispersible Tablets 100 mg	M/s Lupin Limited	Firm presented their proposal for grant of permission to manufacture and marketing of Isoniazid Dispersible Tablets 100 mg (additional dosage form) for indicated in combination with other tuberculosis medicines for the treatment of tuberculosis due to Mycobacterium tuberculosis, including in regimens for drug resistant tuberculosis along with Bioequivalence study report (Study No.: LBC-23-043, Version No.: 00, Date: 14 Dec 2023) under fasting conditions. After detailed deliberation, the committee recommended to accept the Bioequivalence study report and recommended for grant of permission to manufacture and marketing of Isoniazid Dispersible Tablets 100 mg.
3.	SND/CT/21/000028 Remdesivir Injection 100mg/20ml [5mg/ml]	M/s JSS Medical Research Asia Pacific Private Limited	Firm presented Phase IV clinical trial report before the committee. After detailed deliberation, Committee noted and agreed the results w.r.t. primary objective i.e. safety and tolerability result of Phase IV clinical trial report.
FDC Division			
4.	FDC/MA/24/000264 Piperacillin 4gm + Tazobactam Injection	M/s GUFIC BIOSCIENCES LIMITED	The firm presented their proposal along with justification for BE & Phase III CT waiver before the committee.

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	IP 500 mg + Sodium chloride Injection IP 0.9%w/v 100ml in dual chamber Bag		After detailed deliberation, the committee opined the following: 1. The strength of diluent i.e. Sodium chloride injection 0.9%w/v is different from similar USFDA approved product. 2. The firm should present more scientific literature available from peer reviewed journal in support of the proposed FDC with Sodium chloride injection 0.9%w/v. Accordingly, the firm should submit the above justification for further review by the committee.
5.	FDC/MA/25/000010 Combikit of Amoxycillin and Potassium Clavulanate Oral Suspension IP(600 mg + 42.9 mg) with one ampoule containing 60 mL Sterile Purified Water U.S.P. (for reconstitution of dry syrup)	M/s Medreich Limited,	The firm presented their proposal along with justification for BE & Phase III CT waiver before the committee. The committee noted that Combipack aims to enhance patient compliance and convenience. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed Combipack with the condition that Active PMS study should be conducted. Accordingly, Active PMS study protocol should be submitted within 03 months after approval for further review by the committee.
6.	FDC/MA/25/000047 Vitamin C IP 500mg + Vitamin D3 IP 2000IU chewable tablet	M/s. Abbott Healthcare Pvt. Ltd	The firm presented the proposal before the committee. After detailed deliberation, the committee opined the following: 1. The firm did not present adequate justification/rationale for the proposed FDC as a drug and its significant benefits 2. Published scientific literature in peer reviewed journal in support of essentiality and desirability of proposed FDC is not presented. 3. Firm was not able to present justification on selection of

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			strength of Vitamin D3 in the proposed FDC 4. The proposed FDC is not approved internationally 5. The firm did not present Published scientific literature of FDC for proposed indication. Accordingly, the firm should submit above data/ documents for further review by the committee.