Recommendations of the SEC (Antimicrobial & Antiparasitic) made in its 06th/26 meeting held on 11.06.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/25/000181 Octenidine dihydrochloride 0.1% + 2-phenoxyethanol 2% solution	M/s. Sirmaxo Chemicals Pvt. Ltd.	The firm presented the proposal for grant of permission for manufacture and market of the drug Octenidine dihydrochloride 0.1% + 2-phenoxyethanol 2% solution along with request for Phase- III clinical trial waiver before the committee. After detailed deliberation, the committee noted that one of ingredient of proposed FDC i.e. Octenidine dihydrochloride is not approved in India & the proposed indication does not falls under unmet medical need. Hence, committee did not agree for Phase III Clinical Trial waiver and recommended that firm should submit Phase III CT protocol to CDSCO for further review by the committee.
SND Division			
2.	SND-16011(11)/6/2026-eoffice Liposomal Amphotericin B Injection 50mg/vial (Lyophilized)	M/s. Emcure Pharmaceuticals Limited.	The firm presented the amended Active PMS protocol vide No. CT/22/010, Ver. No 1.0, dated 24.02.2026 before the committee. After detailed deliberation, the committee recommended the following changes to the Active PMS Protocol - 1. Inclusion Criteria No. 02 should be revised to ensure that patients are enrolled prospectively, rather than including patients who are already receiving treatment with Liposomal Amphotericin B Injection 50 mg/vial (Lyophilized). 2. The exclusion criteria No. 4 stating, 'In the last six weeks, patients have taken any Amphotericin B preparation other than TRASPOR®,' should be revised to exclude all patients who are already receiving treatment with any Amphotericin B. 3. The proposed study indication should be revised in accordance with the data available from the National Centre for Disease Control (NCDC), and the

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			sample size should be increased accordingly. Accordingly, the firm is required to submit revised protocol incorporating the above recommendations for further evaluation by the SEC.
FDC Division			
3.	FDC/MA/25/000074 Ceftriaxone Sodium IP (Sterile) eq. to Ceftriaxone 1000mg + Avibactam Sodium (Sterile) 551mg eq. to Avibactam 500mg per vial injection	M/s. Malik Lifesciences Pvt. Ltd.	The firm did not attend the meeting.
4.	FDC/MA/26/000064 Ceftriaxone Sodium IP eq. to Ceftriaxone 1g + Sulbactam Sodium IP eq. to Sulbactam 1g per vial Powder for injectable solution	M/s. Aristo Pharmaceuticals Private Limited.	The firm presented the proposal before the committee. After detailed deliberation, the committee opined that: 1. Firm did not present any Scientific valid rational for the combination. 2. There is no synergy and does not add any meaningful antibacterial benefit. 3. Firm did not justify the breakpoint for clinical relevance to antimicrobial resistance. 4. There is chance of antibacterial resistance for Acinetobacter infections, the combination behaves more like sulbactam therapy with an inactive ceftriaxone companion. Hence, the committee did not recommend for approval of proposed FDC.
5.	FDC/MA/24/000083 Meropenem Trihydrate IP (Sterile) eq. to Anhydrous Meropenem 1000mg + Sodium Carbonate eq. to Sodium 90.2mg + Avibactam Sodium (Sterile) eq.to Avibactam 500mg injection	M/s. Akums Drugs and Pharmaceutical Limited.	In light of the earlier SEC recommendation dated 10.04.2024, the firm presented the proposal along with justification before the committee. After detailed deliberation, the committee opined that: 1. Firm did not present any advantage over already approved FDC. 2. The microbiological breakpoint of the combination is also not available.

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			3. The proposed FDC is not approved internationally. Hence, the committee did not recommend for approval of the proposed FDC.
6.	FDC/MA/25/000209 Avibactam Sodium (Sterile) eq. to Avibactam 500 mg + Meropenem Trihydrate (Sterile) IP eq. to Meropenem 1000 mg Injection	M/s. Protech Telelinks	The firm presented the proposal along with justification before the committee. After detailed deliberation, the committee opined that: 1. Firm did not present any advantage over already approved FDC. 2. The microbiological breakpoint of the combination is also not available. 3. The proposed FDC is not approved internationally. Hence, the committee did not recommend for approval of the proposed FDC.