Recommendations of the SEC (Antimicrobial & Antiparasitic) made in its 05th/26 meeting held on 07.05.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	BABE/CT05/FF/2025/53019 Tenofovir Alafenamide 90 mg Tablet	M/s. Veeda Clinical Research Limited	In light of the earlier SEC recommendation dated 11.03.2026, the firm presented the Protocol No. 25-VIN-0361 Version No. 01 Protocol Date 21-JUL-2025, Amendment 001 Date 28-MAR-2026. After detailed deliberation the committee recommended for conduct of proposed BE study for export purpose only.
New Drugs Division			
2.	ND/CT/20/000108 Pretomanid Tablets 200 mg	M/s. Mylan Laboratories Limited	Under Discussion
3.	ND/MA/26/000009 Lenacapavir Injection 463.5 mg/ 1.5 mL (309 mg/mL)	M/s. Dr. Reddy's Laboratories Limited	The firm did not attend the meeting.
4.	ND/CT/24/000004 Tafenoquine 50 mg and 150 mg Tablets	M/s. Glaxosmithkline Pharmaceuticals Limited	The firm presented their proposal for amendment in Phase-III CT protocol of Tafenoquine Tablets 50 mg and 150 mg (Amended Protocol no. 208550, Version 05 dated 23.02.2026), before the committee. After detailed deliberation, the committee agreed for the amendment of protocol as presented by the firm.
SND Division			
5.	SND/MA/24/000188 Polymyxin B for injection IP 10,00,000 IU	M/s. Venus Remedies Limited	The firm did not attend the meeting.
6.	SND/IMP/25/000118 Bedaquiline tablets 20 mg and 100 mg	M/s. Johnson & Johnson Pvt. Ltd	The firm presented the proposal for grant of permission to import and marketing of Bedaquiline tablets 20 mg and 100 mg for expansion of indication i.e. as part of combination therapy in adult (≥18 years) and pediatric patients (2 years to less than 18 years of age and weighing at least 7 kg) with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to at least rifampicin and isoniazid along with justification for local clinical trial waiver before the committee.

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			Committee noted that, in India Bedaquiline tablets 100mg was approved in 2015 for the indication -In adults (18 years), A part of combination therapy of pulmonary tuberculosis due to multi-drug resistant Mycobacterium tuberculosis when an effective treatment regimen cannot otherwise be provided, and Bedaquiline tablets 20mg was approved in 2021 for the indication - In adult (18 years) and pediatric patients (5 years to less than 18 years of age and weighing at least 15 kg) as part of combination therapy of pulmonary tuberculosis (TB) due to multi-drug resistant Mycobacterium tuberculosis. Also noted that, the proposed expanded indication was approved in United States and European union in 2025. After detailed deliberation, the committee recommended for grant of permission to import and marketing of Bedaquiline tablets 20 mg and 100 mg for proposed expanded indication subject to same condition of conditional access through NTEP as approved earlier.
FDC Division			
7.	FDC/IMP/21/000001 Hydrogen Peroxide 1%w/w + Paracetic acid 0.07%w/w + Acetic acid 5.07%w/w liquid Disinfectant	M/s. Sterimed Inc.	The firm presented their proposal along with justification for BE waiver & Phase III CT waiver before the committee. The committee opined that: 1. Material Safety Data sheet should mention about the care to be taken after accidental exposure. 2. Firm should submit validated sporicidal activity from approved labs. 3. Firm should submit non-clinical safety data. 4. Composition and Indication are not in-line with innovator product. Accordingly, the firm should submit the above data to CDSCO for further review by the committee.
8.	FDC/MA/25/000073 Cefoperazone Sodium IP (Sterile) eq. to Cefoperazone 1000 mg	M/s. Malik Lifesciences Pvt. Ltd.	The firm presented the proposal along with Phase III CT protocol before the committee. After detailed deliberation, the committee

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	+ Avibactam Sodium (Sterile) 551 mg eq. to Avibactam 500 mg per vial injection		considered the rationality of the proposed FDC and recommended for grant of permission to conduct Phase III CT study with the condition that more government sites should be included and the sites should be geographically distributed. Accordingly, the firm should submit Phase III CT report to CDSCO for further review by the committee.