

Recommendations of the SEC (Antimicrobial & Antiparasitic) made in its 01st/26 meeting held on 08.01.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	BABE/CT05/FF/2025/50913 Artemether 20mg, Lumefantrine 120mg and Amodiaquine 40mg Dispersible Tablets	M/s. Macleods Pharmaceuticals Ltd.,	Firm presented the BA/BE study Protocol No. BEQ-3972-ALA F-2024 Version No. 01 Protocol Date 23-JUN-2025 for export purpose only before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only
New Drugs Division			
2.	ND/CT/25/000074 Letermovir Tablets 240 mg and 480 mg	M/s Zydus Lifesciences Limited	In the light of earlier SEC recommendation dated 16.09.2025, the firm presented revised Phase-IV CT protocol (Protocol C2B05804; Version 02 dated 15.10.2025), before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial w.r.t. indication for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT), as per the protocol presented.
3.	ND-11012(19)/19/2025-eoffice Pretomanid Tablets 200 mg	M/s. Mylan Laboratories Ltd.	The firm presented their proposal for Amendment in Package Insert of Pretomanid Tablets 200 mg (Revision dated: May 2025), before the committee. After detailed deliberation, the committee recommended for update of Prescribing Information as presented by the firm.
4.	ND/CT/24/000058 Cefepime 2gm and Enmetazobactam 500 mg Dry Powder	M/s ORCHID PHARMA LIMITED	The firm presented updates proposed in Phase IV CT study Protocol w.r.t. terminology (such as replacing randomization with enrolment), clarifications to inclusion/exclusion criteria, Refinement of outcome definitions and assessment schedules etc., before the committee. After detailed deliberation, the committee considered the proposed changes in Phase IV clinical trial protocol. The firm should submit updated copy of

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			Phase IV clinical trial protocol to CDSCO
SND Division			
5.	SND/CT/25/000146 Pretomanide Tablets 200 mg	M/s.Macleods Pharmaceuticals Ltd.	Under Discussion.
6.	SND/MA/25/000127 Posaconazole 300 mg Gastro-Resistant Tablets	M/s. AET LABORATORIE S PRIVATE LIMITED	Under Discussion.
7.	SND/IMP/25/000118 Bedaquiline tablets 20 mg and 100 mg	M/s Johnson & Johnson Pvt. Ltd	The firm did not attend the meeting.
8.	SND/MA/22/000210 Meropenem Injection IP 125 mg	M/s. Aristo Pharmaceuticals Private Limited	The firm did not attend the meeting