

Recommendations of the SEC (Antimicrobial & Antiparasitic) made in its 02nd/26 meeting held on 10.02.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT/24/000010 Inosine Pranobex 500 mg/ 1000 mg Tablets	M/s. Themis Medicare Ltd.	The firm presented Phase IV clinical trial report of Inosine Pranobex 500 and 1000 mg Tablets (CSR: TML/IAD/05, Version 01, Dated 28-OCT-2025), before the committee. After detailed deliberation, the committee considered the result of the Phase IV clinical study.
2.	ND/MA/25/000117 & ND/MA/25/000118 Delafloxacin Injection 300 mg/vial and Delafloxacin Tablets 450 mg	M/s. Sun Pharma Laboratories Limited.	In the light of earlier SEC recommendation dated 15.10.2025, the firm presented revised Phase-III CT protocol (Protocol no. ICR/25/015, Version No.: 2.0; Date 19/DEC/2025) for the indication ABSSSI, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial with the condition that patients with the increase in QT prolongation more than 60 m Sec from baseline, should be discontinued from the study. Accordingly, the firm should submit revised CT protocol to CDSCO.
3.	ND/CT/25/000130 Doravirine Tablets 100 mg	M/s. Emcure Pharmaceuticals Limited.	In line with the condition of permission for manufacture and market of the drug, Doravirine Tablets 100 mg, the firm presented Phase IV clinical trial protocol (Protocol No CE-25-04, Version No: V1.0 dated 17-Jun-2025) before the committee. After detailed deliberation, committee recommended for grant of permission to conduct Phase IV clinical trial as per the protocol presented by the firm. The results of Phase IV Clinical Trial should be submitted to CDSCO for further review by the committee.
SND Division			
4.	SND/MA/21/000224 & SND-11011/71/2025-eoffice	M/s. Natco Pharma Ltd.	The firm presented the report of active PMS study for the drug Liposomal Amphotericin B Injection 50 mg/vial for the indicated for the treatment of patients with Invasive fungal infection, before the

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	Liposomal Amphotericin B Injection 50mg/vial		Committee. After detailed deliberation, the Committee recommended to accept the Active PMS study report as presented by the firm.
5.	SND-11011/70/2025-eoffice Liposomal Amphotericin B Injection 50 mg/vial	M/s. BDR Pharma	The firm presented the report of active PMS study for the drug Liposomal Amphotericin B Injection 50mg/vial for the Indicated for the treatment of invasive fungal infection in patients who are refractory to or intolerant of conventional Amphotericin B therapy, before the Committee. After detailed deliberation, the Committee recommended to accept the Active PMS study report as presented by the firm.
6.	File No.:SND-11011/73/2025-eoffice Isavuconazole (As Isavuconazole Sulphate) 200 mg Powder	M/s. BDR Pharmaceuticals International Pvt Ltd	Firm did not present the protocol & therefore, Proposal deferred for next meeting.
7.	SND/MA/21/000223 Liposomal Amphotericin B Injection 50 mg/vial (Lyophilized)	M/s. Gufic Biosciences Limited	In light of earlier SEC recommendation dated 19.08.2025, firm presented revised Active PMS Study protocol, before the Committee. After detailed deliberation, the Committee recommended for approval of amended protocol to conduct Active PMS Study as presented by the firm.
FDC Division			
8.	FDC/MA/22/000405 Rifapentine 150 mg + Isoniazid 150 mg tablets	M/s. J Duncan Healthcare Pvt. Ltd.	The firm did not attend the meeting.