

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 13th/25 meeting held on 09.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/21/000463 Isavuconazole 200 mg powder for concentrate for solution for infusion	M/s. Gufic Biosciences Limited.	The firm has presented the Protocol (Protocol No.: CRS/25/008, Version 1.0, Dated 20 November 2025) to conduct PMS study with study titled “A Multicenter, Open label, Non-Comparative, Interventional, Prospective, Active Post Surveillance Study to evaluate safety and effectiveness of Isavuconazole (as Isavuconazonium sulfate) 200 mg infusion in Indian Patients with Invasive Aspergillosis and Invasive Mucormycosis.” before the committee. After detailed deliberation, the committee recommended to conduct the PMS study as per protocol presented by the firm.
2.	SND/CT/25/000108 Povidone Iodine 0.5% w/v Nasal Spray	M/s. G. S. Pharmbutor Private Ltd.	The firm presented the proposal to conduct Active Post-Marketing Surveillance (PMS) Study of Povidone Iodine 0.5% w/v Nasal Spray vide Protocol ID.CT-NS-IR-2025, Version 1.0 Dated 18 June 2025 before the committee. After detailed deliberation, the committee recommended for approval to conduct the Active Post-Marketing Surveillance (PMS) Study as per protocol presented by the firm.
3.	SND/MA/24/000074 Amoxicillin Dispersible Tablets 500 mg and 1000 mg	M/s. Aurobindo Pharma Ltd.	The firm did not turn up for the presentation.
4.	SND/MA/24/000228 Fosfomycin Trometamol BP 3.000 gram Powder	M/s. SRS Pharmaceuticals Pvt. Ltd.	In light of earlier SEC recommendation dated 15.07.2025, The firm presented the Phase III clinical trial report with additional information for the efficacy results in correlation with microbial culture testing including the Fosfomycin resistant microbes performed in Chronic Bacterial

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			<p>Prostatitis (CBP) before the committee.</p> <p>After detailed deliberation, the committee recommends to grant permission for manufacture and marketing of Fosfomycin Trometamol BP 3 g Powder for the treatment of Chronic Bacterial Prostatitis and Chronic Prostatitis/Chronic Pelvic Pain Syndrome, subject to condition that the firm should conduct Phase IV clinical Trial.</p> <p>Accordingly, the firm should submit the Phase IV clinical trial protocol to CDSCO within 3 months from date of approval of the drug product for further review by the committee</p>
5.	SND/MA/22/000210 Meropenem Injection IP 125 mg	M/s. Aristo Pharmaceuticals Private Limited.	The firm did not turn up for the presentation.
6.	SND/MA/25/000218 Cidofovir Topical Gel 1% and Cidofovir TopicalGel 3 %	M/s. Emcure Pharmaceuticals Limited.	The firm did not turn up for the presentation.
FDC Division			
7.	FDC/CT/25/000059 Aztreonam 1.5 gm + Avibactam 0.5 gm Powder for concentrate for solution for infusion	M/s. Pfizer Limited.	<p>In light of the condition mentioned in permission in Form CT-23 dated 05.03.2025; the firm presented the Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial with following conditions:</p> <ol style="list-style-type: none"> 1. Firm should include not less than 200 subjects. 2. Firm should also define the criteria for proving that this is suspected patients. 3. Firm should include more Government sites.

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			Accordingly, the revised Phase IV Clinical Trial protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase IV Clinical Trial report for further review by the Committee.