

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 10th/25 meeting held on 16.09.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	IMP/MD/2025/146084 Antimicrobial wound dressing with copper oxide)	M/s B L Lifesciences Pvt. Ltd.	The firm did not turn up for the presentation.
New Drugs Division			
2.	ND/CT/25/000074 Letermovir Tablets 240 mg and 480 mg	M/s Zydus Lifesciences Limited	<p>In line with the condition of the permission for the manufacturing and marketing of the drug Letermovir Tablets 240 mg and 480 mg, firm presented Phase IV clinical trial protocol of drug Letermovir tablets 240 mg and 480 mg vide Protocol no. C2B05804, Ver. 1.0 (dated 28.05.2025), before the committee.</p> <p>The committee noted that permission to manufacture and market of drug Letermovir tablets 240 mg and 480 mg was issued for the following two indications:</p> <p>1). For prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).</p> <p>2). For prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/ Recipient CMV seronegative [D+/R-]).</p> <p>However, in the presented protocol firm has proposed the study to assess the safety and efficacy of drug Letermovir tablets 240 mg and 480 mg for only one indication i.e. For prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).</p> <p>Also, the committee noted that the proposed sample size of 40 patients is not adequate.</p> <p>After detailed deliberation, the committee</p>

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			<p>recommended that firm should revise the sample size with justification.</p> <p>The committee also opined that primary outcome should be measured with DNA PCR instead of IgG.</p> <p>Accordingly, firm should submit revised CT protocol within one month for further review by the committee.</p> <p>Further, the committee recommended that firm need to submit Phase-IV study protocol for the second indication i.e. For prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/ Recipient CMV seronegative [D+/R-].</p>
SND Division			
3.	SND/IMP/21/000058 Chlorine-based disinfectant concentrate 53.000 % W/W tablet	M/s Ecolab Food Safety And Hygiene Solutions Private Limited	The firm did not turn up for the presentation.
4.	SND/CT/25/000095 Clarithromycin Extended Release Tablets 1000	M/s Abbott Healthcare Pvt. Ltd	<p>The firm presented CT Protocol for conduct Phase-IV clinical trial Study of Clarithromycin Extended Release Tablets 1000 mg before the Committee.</p> <p>After detailed deliberation, the committee recommended to include following parameters in the protocol presented by the firm:</p> <ol style="list-style-type: none"> 1. Follow up period should be of 2 weeks after 3rd visit. 2. QT prolongation monitoring in safety assessment parameters. 3. Define KFT/LFT in protocol. 4. CT sites should be geographically distributed including at least 50% of government sites. 5. Update exclusion criteria: Coronary artery disease patient will be excluded. <p>Accordingly, firm should submit revised Phase IV clinical trial to CDSCO.</p>

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5.	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.
6.	SND/MA/22/000210 Meropenem Injection IP 125 mg	M/s. Aristo Pharmaceuticals Private Limited	The firm did not turn up for the presentation.
FDC Division			
7.	FDC/MA/24/000082 Soybean Oil USP 6 gm + Medium Chain Triglycerides USP 6 gm + Olive Oil USP 5 gm + Fish Oil BP 3 gm per 100 mL solution for infusion (Lipid Injectable Emulsion USP 20% w/v)	M/s Aculife Healthcare Private Limited	The firm did not turn up for the presentation.