

**Recommendations of the SEC (Gastroenterology & Hepatology) made in its 03<sup>rd</sup>/25 meeting held on 17.03.2025 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/18/25 Online Submission (47909)  SAR441566	M/s Sanofi Healthcare India Private Limited	The firm presented phase II clinical study Protocol no. DRI17822 Amendment number 01 Version 01 Dated 19 Dec 2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/21/25 Online Submission (48056)  RABI767	M/s JSS Medical Research Asia Pacific Private Limited	The firm presented phase IIa clinical study Protocol no. RABI-767-201 amendment 3 version 4.0 dated 10-February-2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
<b>Medical Devices Division</b>			
3.	File No.: MED-14/1/2025-coffice (Form MD-23 Permission # CI/MD/2023/000034)  Device name: EBDLR – Extracorporeal Bioengineered Dual- Cell Liver Regeneration System (Liver assist device)	M/s. Ardent Clinical Research Pvt. Ltd.	The firm presented the revised Clinical study Protocol number 001-EBDLR-YLSPLT-2023 with version 3.0 by amending the inclusion & exclusion criteria, target population, etc for ongoing study on the said device.  After detailed deliberation, the expert committee recommended for continuing the study with the revised study protocol version 3.0 dated 13-11-2024, as proposed by the applicant.
<b>New Drugs Division</b>			
4.	12-01/25-DC (Pt-05)  Obeticholic acid 5mg/10mg tablets	1.M/s Dr. Reddys's Laboratories Limited, 2. M/s Akums Drugs & Pharmaceuticals Limited, 3. M/s Synokem Pharmaceutical	The firms presented the matter on safety of Obeticholic acid 5mg/10mg tablets before the committee in view of the consideration of revocation of approval by EMA (European Medicines Agency).  After detailed deliberation, the committee recommended that the firms should submit and present the current prescribing

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		Limited, 4. Indorama Healthcare Pvt. Ltd, 5. Alkem Laboratories Ltd, 6. Theon Pharmaceuticals Ltd, 7. G.C.Chemie Pharmie Ltd, 8. Logos Pharma, 9. Mascot Health Series Private Limited, 10. Optimus Pharma Private Limited, 11. MSN Laboratories Private Limited	information and PSURs for further review by the committee.  Note: The firm present in the deliberation are: <ol style="list-style-type: none"> <li>1. Alkem Laboratories Ltd</li> <li>2. Optimus Pharma Private Limited</li> <li>3. M/s Dr. Reddys's Laboratories Limited</li> <li>4. MSN Laboratories Private Limited</li> <li>5. M/s Synokem Pharmaceutical Limited</li> </ol>
5.	ND/CT/24/000081  Tegoprazan tablet 50 mg	M/s Hetero Labs Limited	The firm presented proposal for grant of Phase-III Clinical Trial of Tegoprazan tablets 50 mg along with Bioequivalence study protocol and Phase III clinical trial protocol before the Committee.  After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study and Phase III clinical trial, as per the protocol presented.  Further, the committee opined that the firm should submit Bioequivalence study report to CDSCO for review by the committee before initiating the Phase III clinical trial.
6.	12-10/12-DC (Pt- 9 Akums/Ademetionine )  Ademetionine Tablets	M/s Akums Drugs & Pharmaceuticals Ltd.	The firm presented Phase IV clinical trial report of drug Ademetionine Tablets before the committee.  After detailed deliberation, the committee noted that there is a subgroup analysis of serum ALT values available for 245 patients with Fatty liver, 2 patients each with Alcoholic hepatitis and Alcoholic cirrhosis, and did not accept the results of the study.

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			<p>The committee recommended that the firm should submit the structured Phase-IV Clinical Trial Protocol of Ademetionine Tablets, with three-arm to include patients with Fatty Liver, Alcoholic hepatitis and Alcoholic cirrhosis.</p> <p>Accordingly, the firm should submit Phase-IV Clinical Trial Protocol to CDSCO within two months for further review by the committee.</p>
7.	ND/MA/24/000173  Resmetirom Tablet (60 mg, 80 mg & 100 mg)	M/s Ravenbhel Biotech	<p>The firm presented their proposal for grant of permission to manufacture and market Resmetirom Tablets 60mg/ 80 mg /100 mg along with BE study (Protocol No VRL-24-049, Version-01, dated: 16.12.2024) and Phase III Clinical Trial study before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct bioequivalence study as per protocol presented. Further, the committee opined that:</p> <ol style="list-style-type: none"> <li>1 Firm should include Resmetirom 60 mg arm under the proposed Phase III CT protocol.</li> <li>2. Firm should include Liver biopsy as one of the evaluation criteria at recruitment stage and at the end of study.</li> </ol> <p>Accordingly, the firm should submit revised Phase III Clinical Trial Protocol to the committee for further consideration.</p>
8.	ND/MA/24/000127  Resmetirom Tablet (60 mg, 80 mg & 100 mg)	M/s Morepen Laboratories Limited	<p>Firm presented proposal for grant of permission to manufacture and market of new drug Resmetirom Tablet along with Bioequivalence study protocol and justification for local Phase III clinical trial waiver before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to</p>

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			<p>conduct Bioequivalence study as per the protocol presented.</p> <p>However, the committee did not recommend for the local Phase III clinical trial waiver and recommended to submit Phase III clinical trial protocol for further consideration by the committee.</p>
9.	ND/MA/24/000062  Vonoprazan tablets 10/20 mg	M/s Exemed Pharmaceuticals	<p>Firm presented proposal for grant of permission to manufacture and market of new drug Vonoprazan tablets along with Bioequivalence study protocol before the committee.</p> <p>After detailed deliberation, the committee noted that new drug Vonoprazan is already approved in the country for manufacture and market. Accordingly, the committee recommended for grant of permission to conduct Bioequivalence study as per the protocol presented.</p>