Recommendations of the SEC (Gastroenterology & Hepatology) made in its 02nd/25 meeting held on 27.02.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/141/24 Online Submission (46446) RO7790121	M/s Roche Products (India) Private Limited	The firm presented phase 3 clinical study protocol no. GA45331 version 1.0 dated 01 August 2024. After detailed deliberation, the committee opined that the firm should submit phase 1 and phase II data for Crohn's disease for further review by the committee. Dr. Vineet Ahuja did not participate for the said proposal.
2.	CT/142/24 Online Submission (46507) RO7790121	M/s Roche Products (India) Private Limited	The firm presented phase 3 clinical study protocol no. GA45332 version 1.0 dated 22 August 2024. After detailed deliberation, the committee opined that the firm should submit phase 1 and phase II data for Crohn's disease for further review by the committee. Dr. Vineet Ahuja did not participate for the said proposal.
SND Division			
3.	SND/MA/23/000086 Rabeprazole Sodium Modified Release Capsules 40 mg	M/s. Dr. Reddy's Laboratories Limited	In light of earlier SEC recommendations dated 21.03.2024, the firm has presented comparative bioavailability study report and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee considered the comparative bioavailability study report and recommended for grant of permission to conduct Phase III clinical trial study as per the protocol presented by the firm.
4.	SND/CT/23/000068 Amisulpride Injection 5mg/2ml	M/s La Renon Healthcare Pvt. Ltd.	The firm did not turn up for the presentation.

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5.	SND/CT/24/000097 Esomeprazole Dual-Release Gastro-Resistant Tablets 80mg	M/s Sun Pharma Laboratories Limited	The firm presented their proposal for grant of permission to conduct Phase-IV clinical trial of Esomeprazole Dual release gastro-resistant tablets 80mg along with Phase-IV clinical trial protocol before the Committee. After detailed deliberation, the Committee opined that, the proposed protocol does not address all the aims of phase IV clinical trial such as sudden discontinuation of treatment, long term follow-up etc. Also, firm is required to include the adequate method for assessment of long-term effect of drug by means of specific questionnaires or by pH metry study. Further, it is recommended to add more study sites including at-least one government site. Accordingly, the firm should submit revised Phase-IV protocol preferably within one month to CDSCO for further review by the Committee
6.	SND/IMP/24/000098 Saccharomyces Boulardii CNCM-I 745 500mg Powder in Sachet (For Oral Suspension)	M/s. Dr. Reddy's Laboratories Limited	Firm presented the proposal for import and market of Saccharomyces Boulardii CNCM-I 745 500mg Powder in Sachet (For Oral Suspension) for the - Treatment of acute infectious diarrhoea in adults and children. - Prevention and treatment of antibiotic associated colitis and diarrhoea. - In addition to vancomycin/ metronidazole treatment to prevent recurrence of Clostridium difficile disease (CDD). - Supportive in the treatment of diarrhea occurring in irritable bowel syndrome (IBS). along with justification for BE waiver and CT waiver before the committee. The committee noted that applied drug

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			product was approved in USA, Europe and Canada. After detailed deliberation, the committee recommended for grant of import and market of Saccharomyces Boulardii CNCM-I 745 500mg Powder in Sachet (For Oral Suspension) with bioequivalence study waiver and clinical trial study waiver with condition to conduct Phase IV clinical trial study. Accordingly, the firm should submit Phase IV clinical trial study protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee.
7.	SND/MA/24/000216 Prucalopride oral solution 0.2mg/ml	M/s Torrent Pharmaceuticals Ltd	The firm presented their proposal for grant of permission to manufacture and marketing of Prucalopride oral solution 0.2mg/ml along with justification for waiver of Phase-III clinical trial and Bioequivalence study protocol before the Committee. The firm has informed that they are already holding MA permission for Prucalopride tablets 1mg & 2mg issued by CDSCO on 13.04.2017 for the same indication. However, applied formulation Prucalopride oral solution 0.2mg/ml is not yet approved anywhere in the world. After detailed deliberation, the committee recommended grant of permission to conduct BE study as per protocol (Protocol No.: PK-24-036, Version No.: 01 Date: 17.08.2024) presented by the firm. Further the committee opined that, firm should submit referred literature/study for added excipients (propylene glycol, Glycerol, Sorbitol) regarding any

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			synergistic/agonist effect to the prucalopride on CNS. Firm should submit BE Study report to CDSCO and get evaluated from the Committee for further consideration of clinical trial waiver.
New Drug Division			
8.	ND/MA/24/000162 Resmetirom Tablets 60mg, 80mg & 100mg	M/s Mankind Pharma Ltd.	The firm presented the proposal for grant of permission for manufacturing and marketing of Resmetirom Tablets 60mg, 80mg & 100mg along with protocol for BE study and justification for Phase III clinical trial waiver before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct BE study as per protocol presented by the firm. Further, the committee did not recommend Phase III CT waiver at this stage. The firm is required to submit published clinical data preferably in Indian and Southeast Asian population alongwith BE study report for further review by the committee.
FDC Division			
9.	FDC/MA/25/000013 Diastase (1:800) 50mg + Papain 25mg + Compound Cardamom Tincture 0.0750 ml oral liquids	M/s Mendine Pharmaceuticals Pvt. Ltd.	The firm did not turn up for the presentation.