Recommendations of the SEC (Gastroenterology & Hepatology) made in its 11th/25 meeting held on 29.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/49/23 Online Submission (40214) PB016 (Vedolizumab) Powder for Concentrate for Solution for Infusion 300 mg	M/s Worldwide Clinical Trials India Private Limited	The firm presented protocol amendment version 3.1 dated 02 June 2025 protocol no. PB016-03-01. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
SND Division			
2.	SND/MA/24/000216 Prucalopride Oral Solution 0.2 mg/mL	M/s Torrent Pharmaceuticals Ltd.	Firm presented proposal for grant of permission to manufacture and marketing of Prucalopride oral solution 0.2mg/ml for the treatment of idiopathic constipation in adults with waiver of Phase-III clinical trial. Firm presented Bioequivalence study report along with justification for synergistic effect of added excipients on CNS in applied formulation. After detail deliberation the committee Opined that, the firm has not presented adequate safety data on synergistic effect of added excipients (Propylene glycol, Glycerol and Sorbitol) with Prucalopride in applied Formulation. Accordingly the Committee did not recommend for waiver of phase III Clinical trial.
3.	SND/MA/23/000245 Tacrolimus Lipid Suspension for Enema 4 mg/vial	M/s Intas Pharmaceuticals Limited	The firm presented their proposal for grant of permission to conduct Active Post Marketing Surveillance Study of Tacrolimus Lipid Suspension for Enema 4 mg/vial in Adult patients with Mild to moderate Left Sided Ulcerative Colitis Refractory to Mesalamine before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Active PMS study as per Protocol Presented (Protocol No. 0287-23

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			ver 01 dated 20/01/2025) with recommendation to include KFT and Blood pressure monitoring in the study volunteers to assess the safety.
New Drugs Division			
4.	ND/MA/25/000067 Eluxadoline Tablets 75 mg/100 mg	M/s Pure & Cure Healthcare Pvt. Ltd.	The firm has presented the proposal for grant of permission to manufacture and marketing of Eluxadoline Tablets 75 mg/100 mg, indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D), 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 the protocol presented by firm. Further, the firm should submit Bioequivalence study report to CDSCO for review by the committee, before initiating the Phase III clinical trial.
5.	12-01/25-DC (Pt-05) Obeticholic acid 5 mg/10 mg tablets	1. M/s Dr. Reddys's Laboratories Limited, 2. M/s Akums Drugs & Pharmaceuticals Limited, 3. M/s Synokem Pharmaceutical Ltd. 4. M/s Indorama Healthcare Pvt. Ltd, 5. M/s Alkem Laboratories Ltd, 6. M/s Theon Pharmaceuticals Ltd, 7. M/s G.C. Chemie Pharmie Ltd, 8. M/s Logos Pharma, 9. M/s Mascot	In light of earlier SEC recommendation dated 17.03.2025, the firm presented the current prescribing information and PSURs before the committee. After detailed deliberation, the committee opined that firm should revise the prescribing information with respect to the safety concerns. Further, firm should conduct PMS study for the approved indication (primary biliary cholangitis). Accordingly, firm should submit PMS study protocol to CDSCO within three months for further review by the committee

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		Health Series Private Limited, 10. M/s Optimus Pharma Private Limited, 11. M/s MSN Laboratories Private Limited	
6.	ND/MA/24/000073 Elobixibat Tablet 5 mg	M/s BDR Pharmaceuticals International Pvt. Ltd.	In light of earlier SEC recommendations dated 12.12.2024, firm presented proposal for grant of permission to manufacture and market of new drug Elobixibat Tablets 5mg along with Bioequivalence study report before the committee. After detailed deliberation, the committee considered BE results presented by the firm and the committee noted that new drug, Elobixibat Tablets 5mg is already approved in the country for manufacture and market. Accordingly, the committee recommended for grant of permission to manufacture & market Elobixibat Tablets 5mg for the chronic constipation (except for constipation associated with organic diseases).
7.	ND/MA/24/000085 Fexuprazan hydrochloride tablets 40 mg	M/s Sun Pharma Laboratories Limited	In light of earlier SEC recommendations dated 12.12.2024 and as per the condition no. 9 of new drug permission for Fexuprazan hydrochloride tablets 40 mg, firm presented active PMS study protocol for the drug Fexuprazan hydrochloride tablets 40 mg, before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct active PMS study for Fexuprazan hydrochloride tablets 40 mg as per the protocol presented
FDC Division			
8.	FDC/MA/25/000008 Lactulose 10 gm + Bacillus coagulans Unique IS-2 2 billion CFU per 15 mL Oral Suspension	M/s Unique Biotech Limited	The firm presented the proposal before the committee. After detailed deliberation, the committee opined that: 1. The firm should submit the approval status of Bacillus coagulans Unique IS-2 2 billion

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			CFU by CDSCO. 2. The firm should submit published scientific literature in peer reviewed journal in support of essentiality and desirability of proposed FDC. 3. The firm should submit literature in peer reviewed journals for safety and efficacy of individual ingredients with compare to FDC (Finished product). 4. The firm should submit international approval status including PMS study data in ICH countries. Accordingly, the firm should submit above data/ documents for further review by the committee.