Recommendations of the SEC (Gastroenterology & Hepatology) made in its 13th/25 meeting held on 24.09.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/107/25 Online Submission (51066) Recombinant Human Serum Albumin (rHSA) 20%	M/s. Shilpa Biologicals Private Limited	The firm presented phase III clinical study Protocol No.: RHSA/SBPL/P3/AB-2025 Version No. 01 dated 21-JUL-2025. After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee. 1. The study protocol shall include clinical endpoint as primary outcome and also include safety evaluation as secondary outcome 2. Primary objective shall include the change of serum albumin concentration after transfusion of 100gm of albumin solution. 3. Secondary end points shall address the reduction of ascites and change in body weight analysis should be standardized based on diuretic dose calculation. 4. The serum Albumin level to be correlated with Serum calcium level obtained from the sample.
2.	CT/114/24 Online Submission (40741) RO7790121	M/s. Roche Products (India) Private Limited	The firm presented protocol amendment version 3 dated 30 Jan 2025 and protocol amendment version 4 dated 12 Jun 2025 protocol no. GA45330. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/113/24 Online Submission (40737) RO7790121	M/s. Roche Products (India) Private Limited	The firm presented protocol amendment version 3.0 dated 30 Jan 2025 and protocol amendment version 4.0 dated 12 Jun 2025 protocol no. GA45329. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/109/25 Online Submission (51111)	M/s. Johnson & Johnson Pvt. Ltd	The firm presented Phase IIb / III clinical study protocol no.: 77242113CRD3001 version no. Amendment 1 dated 16-JUL-2025

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	icotrokinra (JNJ-77242113)		After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
5.	E-52019 & 51972 Vedolizumab 300 mg and 108 mg Powder for concentrate for solution for infusion	M/s. Takeda Biopharmaceuticals India Pvt Ltd	The firm presented the proposal for update in Package Insert for the changes in the Section 4.6 (Use in Special population) of the drug product Vedolizumab 300 mg and 108 mg powder for concentrate for solution for infusion based on the updates in the CCDS Version 9.0. After detailed deliberation, the committee recommended for approval of updated package insert for the proposed changes.
6.	E-52430 Ustekinumab Solution for Injection-Stelara® 90 mg & 45 mg and Ustekinumab Concentrate Solution for Intravenous Infusion - Stelara® 130 mg	M/s. Johnson & Johnson Private Limited	The firm presented the proposal for update in Package Insert for the changes in the sections of Use in special population, Drug interactions, Adverse reactions, pharmacological properties and Pharmaceutical particulars of the drug product Ustekinumab Solution for Injection-Stelara® 90 mg & 45 mg and Ustekinumab Concentrate Solution for Intravenous Infusion -Stelara® 130mg based on the updates in the CCDS Version 50, 51 and 52. After detailed deliberation, the committee recommended for approval of updated package insert for the proposed changes.
New Drug Division			
7.	ND/MA/25/000105 Resmetirom tablets 60 mg/80 mg/100 mg	M/s. Dr. Reddy's Laboratory Limited	Firm presented their proposal for grant of permission for manufacture and market of the drug Resmetirom Tablet 60/80/100 mg. The firm has submitted application along with BE study protocol and Phase-III CT protocol. However, the firm did not present the Phase-III protocol. Firm presented only BE study protocol titled "An open label, balanced, randomized, two-treatment, two-period, two-sequence, single dose, crossover, oral bioequivalence study of test product (T) Resmetirom Tablets 100 mg of Dr. Reddy's Laboratories Limited, India comparing with reference product (R)

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			Rezdiffra (resmetirom) tablets 100 mg of Madrigal Pharmaceuticals, Inc., in normal, healthy, adult human subjects, under fasting condition''.(Protocol No; 060-25, Version 01, dated 14 Apr 2025) for the drug Resmetirom Tablet 60/80/100 mg, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct BE study per the protocol presented. Accordingly, the firm should submit the BE study report to CDSCO for further review by the committee.
SND Division			
8.	SND/MA/24/000216 Prucalopride Oral Solution 0.2 mg/mL	M/s. Torrent Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 29.07.2025, the firm presented safety data on synergistic effect of added excipients (Propylene glycol, Glycerol and Sorbitol) with Prucalopride in applied Formulation before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacture and market of Prucalopride Oral Solution 0.2 mg/mL.
9.	SND/MA/24/000219 Rifaximin sachets 400 mg and 550 mg	M/s. Zenvision Pharma LLP	The firm presented the proposal for grant of permission to manufacture and market of Rifaximin sachets 400 mg and 550 mg along with Bioequivalence study protocol. The committee noted that Rifaximin tablets 400mg is approved on 18.07.2009 for the indication for the treatment of hepatic encephalopathy and Rifaximin Tablet 550 mg is approved on 18.08.2011 for Reduction in Risk of Overt Hepatic Encephalopathy (HE) Recurrence in Patients of years of Age. After detailed deliberation, the committee recommended for grant of permission to conduct bioequivalence study as per protocol presented by the firm. The firm should submit BE report to CDSCO for further necessary action.
FDC Division			
10.	FDC/MA/24/000005	M/s. Akums Drugs &	The firm did not turn up for the presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Domperidone Maleate IP eq. to Domperidone 30 mg (10 mg as immediate release and 20 mg as sustained release) + Pantoprazole Sodium IP eq. to Pantoprazole (As delayed release Tablet) 40 mg uncoated bilayered tablet	Pharmaceuticals Ltd.	