Recommendations of the SEC (Gastroenterology & Hepatology) made in its 12th/25 meeting held on 20.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/71/25 Online Submission (49923) AVT80 (Vedolizumab) 108 mg/0.68 mL solution for injection pre-filled pen	M/s NORWICH CLINICAL SERVICES PVT. LTD	The firm presented phase I clinical study Protocol No.: AVT80-GL-P01 Version No. 2.1 dated 12-MAY-2025. After detailed deliberation, the committee opined that the firm shall submit safety data from other participating countries for further review by the committee
Biological Division			
2.	BIO/CT04/FF/2025/49744 Vedolizumab Solution for Injection, 108 mg/0.68 mL in pre-filled syringe	M/s. INTAS PHARMACEUTICALS LTD	The firm presented the protocol to conduct Phase I study titled "An assessor-blind, randomized, three-treatment, balanced, single subcutaneous dose, phase I, parallel-group, bioequivalence study of biosimilar Vedolizumab (INTP 53.1) of Intas Pharmaceuticals Limited, India with ENTYVIO of Takeda Pharmaceuticals USA, INC., USA and ENTYVIO of Takeda Pharma a/s, Denmark, in normal, healthy, adult human subjects" for export purpose vide Protocol No.: 0057-24,Version No.: 2.1, Dated 27 March 2025). After detailed deliberation, the committee recommended for grant of permission to conduct Phase I study as per the protocol presented by the firm.
3.	BIO/CT04/FF/2025/47781 Certolizumab Pegol 200 mg solution for injection (200 mg/mL) in PFS	M/s. LUPIN LIMITED	The firm presented the protocol to conduct Phase I study titled "A Double Blind, Balanced, Randomized, Single-Dose, Single-Period, Two-Treatment, Parallel Comparative Pharmacokinetics Study of Lupin's Certolizumab pegol with US Licensed Cimzia (certolizumab pegol) in Healthy, Adult, Human Subjects" for export purpose vide Protocol No. LBC-P-015-25 Version: 00 Date: 21 Apr 2025. After detailed deliberation, the committee recommended the firm to conduct the clinical trial with the condition that IGRA test for latent TB should be a part of screening of subjects in the study.

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			Accordingly, the firm should submit revised protocol to CDSCO for further evaluation.
Medical Devices Division			
4.	IMP/MD/2025/144747 Laparoscopic abdominal lifting device (AbGrab)	M/s MEDVICE SOLUTIONS INDIA PRIVATE LIMITED	Under Discussion.
SND Division			
5.	SND/CT/24/000097 Esomeprazole Dual Release Gastro Resistant Tablets 80 mg	M/s Sun Pharma Laboratories Limited	In continuation with earlier SEC (Gastroenterology & Hepatology) recommendation dated 27/02/2025, firm presented revised protocol for Phase-IV clinical trial of Esomeprazole Dual release gastro-resistant tablets 80 mg before the Committee. After detailed deliberation, the Committee recommended to grant the permission to conduct Phase IV clinical trial as per protocol presented by the firm
6.	SND/MA/22/000219 Tofacitinib Extended Release Tablets 11 mg & 22 mg	M/s MSN Laboratories Private Limited	Firm presented their proposal to manufacture and market Tofacitinib Extended Release Tablets 11 mg & 22 mg along with BE study report for export purpose before the committee. After detailed deliberation, the committee recommended that firm should submit the details of BMI of individual subjects recruited in presented BE study for export market. Also, committee noted that earlier SEC while deliberating the proposal of another firm has recommended to recruit subjects with BMI between 18.50 to 25 kg/m^2 in BE study. Accordingly, committee reiterated that the firm should submit the BE study report in subjects having BMI between 18.50 to 25 kg/m^2 for its further review by the committee.
New Drug Division			
7.	ND/MA/24/000062 Vonoprazan tablet 10 mg/20 mg	M/s Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 17.03.2025, the firm presented the BE study report for Vonoprazan Tablets 20 mg before the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Firm presented BE study report including safety parameters, statistical analysis of BE study results. The committee considered the BE study result. The committee noted that drug Vonoprazan Tablets 10/20 mg is already approved in the country for manufacture and market on 08.05.2024. The committee also recommended for grant of permission to manufacture and market of drug Vonoprazan Tablets 10/20 mg for the proposed indication subject to the condition that- (a) The firm should conduct Phase IV clinical trial on Vonoprazan Tablets for which Phase IV CT protocol should be submitted to CDSCO within 3 months of approval for further evaluation by the committee. (b) The drug should be sold by retail on the prescription of a Gastroenterologist only.
8.	ND/MA/24/000173 Resmetirom 60 mg, 80 mg and 100 mg	M/s Ravenbhel Biotech	In light of the earlier SEC recommendation of dated 25.06.2025, firm presented Bioequivalence study report of Resmetirom Tablets 100 mg before the committee. Firm presented BE study report including inclusion / exclusion criteria, safety parameters and statistical data for Bioequivalence study. After detailed deliberation, the committee considered the results of BE study presented by the firm and recommended for grant of permission to initiate Phase III clinical trial for New Drug Resmetirom Tablets 60mg/ 80 mg /100 mg. The firm should submit Phase III clinical trial results to CDSCO for further review by the committee.