Recommendations of the SEC (Gastroenterology & Hepatology) made in its 05th/25 meeting held on 22.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/127/20 Online Submission (38777) Semaglutide	M/s Novo Nordisk India Pvt Ltd	The firm presented protocol amendment version 17.0 dated 31 Jan 2025 protocol no. NN9931-4553. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with condition that the firm shall submit primary end point (72 weeks) study data in Indian subjects
Biological Division			
2.	r-DNA-11016(13)/6/2025-eoffice Vedolizumab 300mg IV	M/s Takeda Biopharmaceuticals India Pvt Ltd	The firm presented the final CSR of Phase IV clinical trial titled "A Multicenter, Single-arm, Open-label, Phase 4 Study to Evaluate the Safety and Efficacy of Vedolizumab in Indian Patients with Ulcerative Colitis and Crohn's Disease" conducted as per Protocol No.: Vedolizumab-4020, Version No. 4.0 Date: 09-NOV-2022. After detailed deliberation, the committee noted the results of the Phase IV clinical trial presented by the firm.
SND Division			
3.	SND/CT/23/000068 Amisulpride Injection 5mg/2ml	M/s La-Renon Healthcare Pvt. Ltd	The firm presented Phase IV Clinical Trial Report (Project no. CT/2023/54) Version 00 dated 06-Nov-2024 as per condition of Permission no. MF/SND/23/000090 dated 06-06-2023 before the committee. After detailed deliberation, the committee accepted the clinical study report presented by the firm.
4.	SND/MA/24/000218 Bacillus clausii UBBC-07 4 billion spore suspension 4.000 billion CFU/ PER 05 ML	M/s Unique Biotech Limited	Firm has presented their proposal for the manufacture and marketing of Bacillus Clausii UBBC-07, 4 billion cfu spore /5ml suspension along with clinical trial waiver for the indication Gut Health. Firm has presented that, 2 billion cfu/5ml already approved at dosage 2 to 4 vials

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			per day amounting 4 to 8 billion cfu/day. Also the proposed strength of Bacillus Clausii UBBC-07, 4 billion cfu spore/5ml is already approved as dietary supplement in India and other countries. Further firm has presented the published literature data of clinical study conducted with proposed strength demonstrating its efficacy in reducing diarrehoea. After detailed deliberation, the Committee opined that, the indication Gut health is wide indication, however the product earlier approved was for treatment of alteration of intestinal bacterial flora at lower strength (2 billion cfu/5ml). Hence, the committee recommended for the grant of permission to manufacture Bacillus clausii UBBC-07, 4 billion cfu spore /5ml suspension indicated for the treatment of alteration of intestinal bacterial flora.
New Drugs Division			
5.	ND/MA/24/000169 Resmetirom Tablet (60 mg, 80 mg & 100 mg)	M/s Exemed Pharmaceuticals	The firm presented the proposal for grant of permission for manufacture and market of the drug Resmetirom Tablets (60 mg, 80 mg & 100 mg) along with BE 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.	ND/MA/23/000130 Upadacitinib Extended Release Tablets 15mg,	M/s MSN Laboratories Private Limited	In light of earlier SEC recommendation dated 13.12.2023, the firm presented the Phase III Clinical trial report for manufacture and marketing of new drug Upadacitinib Extended Release Tablets

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	30mg & 45mg		15mg, 30mg & 45mg before the committee. After detailed deliberation, the committee recommended for the grant of permission for manufacturing and marketing of new drug Upadacitinib Extended Release Tablets 15mg, 30mg & 45mg.
FDC Division			
7.	4-30/2018-DC Sodium Alginate 250mg + Sodium bicarbonate 133.5 mg + Calcium carbonate 80mg Oral Suspension	Reckitt Benckiser Health Limited	The firm did not turn up for the presentation.
8.	FDC/MA/24/000087 L-Isoleucine U.S.P. 0.33 % w/v + L-Leucine U.S.P. 0.4020 % w/v + L-Lysine hydrochloride U.S.P. 0.3190% w/v + L-Methionine U.S.P. 0.2200 % w/v + L-Phenylalanine U.S.P. 0.3080 % w/v + L-Threonine U.S.P. 0.2310 % w/v + L-Trytophan U.S.P. 0.0990 % w/v + L-Valine U.S.P. 0.3190 % w/v + L-Arginine U.S.P. 0.6320 % w/v + L-Histidine U.S.P. 0.2640 % w/v + Glycine U.S.P. 0.5660 % w/v + L-Alanine U.S.P. 1.1380 % w/v + L-Proline U.S.P. 0.3740 % w/v + L-Serine U.S.P. 0.2750 % w/v + L-Tyrosine U.S.P. 0.0220 % w/v solution for infusion	M/s Aculife Healthcare Private Limited	The firm did not turn up for the presentation