Recommendations of the SEC (Gastroenterology & Hepatology) made in its 15th/25 meeting held on 26.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/145/25 Online Submission (52376) Balinatunfib 100 mg	M/s. Sanofi Healthcare India Private Limited	The firm presented phase II clinical study protocol no. LTS19689, version no. 1 dated 08 August 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/136/25 Online Submission (52015) RO7837195 100mg/1ml Powder for solution for injection	M/s. Roche Products (India) Private Limited	The firm presented phase IIb clinical study protocol no. GA45977, version no. 1.0 dated 05 April 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following conditions: 1. Phase I involved single escalating IV doses in volunteers along with two SC exposures. For the Phase IIb study, both IV and SC routes are planned; therefore, safety must be closely monitored following the first IV dose, and global safety data should be submitted before initiating SC dosing. 2. A total of 26 mL + 38 mL of blood will be withdrawn; however, the cutoff hemoglobin level is currently listed as 9 g/dL, which needs to be increased to 11 g/dL
3.	CT/107/25 Online Submission (51066) Recombinant Human Serum Albumin (rHSA) 20%	M/s Shilpa Biologicals Private Limited	In light of earlier SEC recommendation dated 24.09.2025, 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 recommended for grant of permission to conduct the trial as presented by the firm with condition that the rate of infusion shall remain within the permissible limits for patients with decompensated liver disease.

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Biological Division			
4.	E-106404 Itolizumab for Injection (r-DNA origin) 100 mg/vial	M/s. Biocon Limited	The firm presented the final CSR of Phase II clinical trial titled "A phase 2 randomized, double-blind, parallel-group, placebo and active-controlled, two treatment period study to evaluate the safety and efficacy of Itolizumab for the induction of remission in biologics naive patients with moderate to severely active ulcerative colitis" conducted Protocol no. BIOITOLIZ-207, version 1.0, Dated 11-May-2022. After detailed deliberation, the committee noted the results of the Phase II clinical trial presented by the firm.
New Drug Division			
5.	ND/CT/25/000070 Plecanatide Tablets 3 mg	M/s. MSN Laboratories Private Limited	In line with the condition of permission for manufacture and market of the drug, Plecanatide Tablets 3 mg, the firm presented Phase IV clinical trial protocol titled ″ A Phase IV, Open-label, Multicenter, Single Arm Study to Evaluate the long-term safety and Effectiveness, of Plecanatide 3 mg Tablets in Adult Patients with Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C)" (Protocol No: 013/PLCND/MSN/2025 Version 1.0 Dated - 26/MAY/2025) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial as per the protocol presented. The results of Phase IV Clinical Trial should be submitted to CDSCO for further review by the committee.
SND Division			
6.	SND/MA/25/000156 Pioglitazone Tablets 15 mg & 30 mg	M/s. USV Private Limited	The firm presented their proposal for manufacturing and marketing the Pioglitazone Tablets 15mg & 30 mg in Metabolic Dysfunction-Associated Steatotic Liver Disease(MASLD) along with the therapeutic rationale in proposed indication. After detailed deliberation, by considering the side effects of

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			Pioglitazone committee recommended following: 1) Firm should present the systematic review of published literature/ study report of simulated preclinical animal studies. 2) Firm should present systematic review of published literature of clinical studies in Indian Patients in proposed indication. 3) Firm should present the proof of concept for applied drug in Metabolic Dysfunction-Associated Steatotic Liver Disease(MASLD) treatment of Metabolic dysfunction associated steatotic liver disease, in diabetic or non-diabetic adult along with the possible benefit of proposed drug over existing treatments and possible benefit risk evaluation.
7.	SND/CT04/FF/2025/50661 SND/CT/25/000085 Rabeprazole sodium modified release capsule 40 mg	M/s. Dr. Reddy's Laboratories Limited	The firm presented the Phase II clinical trial-proof of concept protocol for the applied product Rabeprazole Sodium Modified Release Capsule 40 mg. The committee opined that the firm has to initiate the already approved Phase III Clinical trial and to submit the interim results of the pH Acid separation data before the committee. After detailed deliberation, the committee opined that the proposed POC protocol for Phase II will be reviewed based on the interim results of the already approved Phase III Clinical Trial protocol.