Recommendations of the SEC (Gastroenterology & Hepatology)made in its 01st/26meeting held on 08.01.2026at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/170/25 Online Submission (53262) LY4268989 (MORF-057), LY3074828 (Mirikizumab)	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd.	The firm presented phase II clinical study Protocol Number: J6E-MC-KWAN, Amendment Number: b dated 27 October 2025. After detailed deliberation, the committee opined that the proposed trial involves the co-administration of LY4268989 (MORF-057) and Mirikizumab. As both agents are immunosuppressive/immunomodulatory, there is a potential risk of additive or synergistic toxicity. Therefore, the firm is required to submit clinical study safety data for the combination regimen, with minimum exposure duration of 12 weeks, for further review by the SEC Committee.
2.	CT/115/25 Online Submission (51359) Icotrokinra (JNJ-77242113)	M/s. Johnson & Johnson Pvt. Ltd.	In light of SEC Recommendation dated 08/10/2025 and dated 11.12.2025, the firm presented phase III clinical trial protocol no. 77242113UCO3001 Amendment 1 dated 24 July 2025. In view of study design, Induction phase is 12 weeks and Maintenance study is 40 weeks (total 52 weeks) and long-term extension study is 248 weeks. Participants who receive Icotrokinra and are non-responders at Week 1-12 will enter the maintenance study from induction phase and continue to receive Icotrokinra daily dosing. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
New Drugs Division			
3.	ND/MA/23/000133 Linaclotide Capsules 290 mcg	M/s. Aurobindo Pharma Ltd.	In the light of earlier SEC recommendation dated 16.01.2024 & 17.01.2024, the firm informed that they have not marketed the product Linaclotide Capsules 290mcg and no PMS data is available. Further, firm has withdrawn the

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			application for manufacturing and marketing of product Linaclotide Capsules 145 mcg for the treatment of chronic idiopathic constipation (CIC). After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Linaclotide 290mcg capsules indicated in adults for the treatment of irritable bowel syndrome with constipation (IBS-C).
4.	12-01/25-DC (Pt-05) Obeticholic acid 5mg/10mg tablets	1. M/s. Dr. Reddys's Laboratories Limited, 2. M/s. Akums Drugs & Pharmaceuticals Limited, 3. M/s. Synokem Pharmaceutical Ltd. 4. Indorama Healthcare Pvt. Ltd, 5. Alkem Laboratories Ltd, 6. Theon Pharmaceuticals Ltd, 7. G.C.ChemiePharmie Ltd, 8. Logos Pharma, 9.Mascot Health Series Private Limited, 10. Optimus Pharma Private Limited, 11. MSN Laboratories Private Limited.	Under Discussion.
SND Division			
5.	SND/MA/23/000215	M/s. La Renon Healthcare Pvt. Ltd.	Under Discussion.

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	Ademetionine 1,4-Butanedisulfonate 500 mg Lyophilized powder for solution for injection		
6.	SND-11011/80/2025 – eoffice Tacrolimus Lipid Tablets 3 mg	M/s. Intas Pharmaceuticals Limited.	The firm did not attend the meeting.
FDC Division			
7.	FDC/MA/25/000008 Lactulose 10 gm + Bacillus coagulans Unique IS-2 2 billion CFU per 15mL Oral Suspension	M/s. Unique Biotech Limited.	In light of the SEC recommendation dated 29.07.2025, the firm presented the proposal along with justification before the committee. After detailed deliberation, the committee noted that- 1. The firm did not present scientific literature published in peer-reviewed journals regarding rationality, essentiality and desirability of the proposed FDC. 2. The proposed FDC is not recommended in any standard therapeutic guidelines. 3. The product is not approved internationally. 4. There is no unmet need of this FDC. 5. Individual drugs are already approved for the proposed indication, and the physicians who want to use both the drugs can any way prescribe these as two separate drugs. In view of above, the committee did not recommend for the approval of the proposed FDC.
8.	FDC/CT/25/000125 Sodium Alginate IP 1000mg + Potassium Hydrogen Carbonate	M/s. Macleods Pharmaceuticals Ltd.	As per the condition mentioned in Form CT-23 dated 25.08.2025, the firm presented active post-marketing surveillance (PMS) protocol before the committee.

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	200mg per 10mL Suspension		After detailed deliberation, the committee recommended for permission to conduct the active PMS study with the condition that: 1. The firm should increase the sample size at least 400. 2. More Government sites should be included and the sites should be geographically distributed. Accordingly, the revised active PMS protocol should be submitted to CDSCOfor review. Further, after approval from CDSCO the firm should submit active PMS report for further review by the committee.