Recommendations of the SEC (Gastroenterology & Hepatology) made in its 01st /25 meeting held on 21.01.25 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/139/22 Online Submission (36545) JNJ-78934804 (guselkumab/golimumab co-formulation	M/s PAREXEL International Clinical Research Private Limited	The firm presented protocol amendment 04 dated 01-Oct-2024 protocol No: 78934804CRD2001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/140/22 Online Submission (36546) JNJ-78934804 (guselkumab/golimumab co-formulation	M/s PAREXEL International Clinical Research Private Limited	The firm presented protocol amendment 4 dated 30-Sep-2024 protocol No: 78934804UCO2001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
3.	E-51352 Adalimumab Injection 40mg/0.8mL and 20mg/0.4mL	M/s. Reliance Life Sciences Pvt Ltd	The firm presented the proposal for update in the package insert of the drug product Adalimumab injection 40mg/0.8mL and 20mg/0.4mL for changes proposed in the sections of Therapeutic indications, Posology and Method of administration. After detailed deliberation, the committee recommended for the approval of updated package insert Version 04 August 2024 for the proposed changes.
4.	E-49547 Infliximab powder For concentrate for solution for infusion 100 mg	M/s. Reliance Life Sciences Pvt Ltd	The firm presented the proposal for update in the package insert of the drug product Infliximab powder for concentrate for solution for infusion 100 mg for changes proposed in the sections of clinical studies and adverse effects. After detailed deliberation, the committee recommended for the approval of updated package insert Version- July 2024 for the proposed changes.
5.	BIO/CT04/FF/2024/45937 Vedolizumab Powder for Concentrate for Solution for Infusion	M/s INTAS PHARMACEUTICALS LTD	The firm presented the proposal to conduct Phase I clinical trial titled "A randomized, double-blind, three-treatment, balanced, single intravenous infusion dose, Phase I, parallel-group, bioequivalence study of biosimilar

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	300 mg/vial		Vedolizumab (INTP 53) 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 male subjects" vide Protocol No. Version No. 3.0 dated 27 September 2024. After detailed deliberation, the committee recommended for approval to conduct the Phase I clinical trial as per protocol presented by the firm.
New Drugs Division			
6.	ND/MA/22/000058 Linaclotide Capsules 72 mcg & 145 mcg	M/s Dr. Reddy's	The firm presented Phase III CT results for the protocol titled "A randomized, Multicentre, double blind, placebo controlled, parallel group, study to evaluate the efficacy and safety of Linaclotide once daily of test product in patients with chronic constipation." before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of the drug Linaclotide Capsules 72 mcg & 145 mcg in the indication of Chronic Idiopathic Constipation (CIC) in adults only. The committee did not recommend two capsules of 145 mcg to be used for Irritable Bowel Syndrome with Constipation (IBS-C) in adults. The committee recommended that the firm is required to develop 290 mcg Linaclotide capsules for IBS-C in adults. In view of above, the firm is required to submit the revised package insert with respect to following points: 1) CIC: 145 mcg orally once daily or 72 mcg orally once daily based on individual presentation or tolerability. 2) The firm should delete the IBS-C indication from the package insert.
SND Division			

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7.	SND/MA/24/000014 Esomeprazole Magnesium DR capsules 40mg	M/s Dr. Reddy's Labs	The firm presented the proposal for grant of permission to manufacture and market of Esomeprazole Gastro Resistant capsules IP 40 mg along with BE study report and justification for wavier of clinical trial study. After detailed deliberation, Committee recommended for grant of permission to manufacture and market of Esomeprazole Gastro resistant capsules IP 40 mg in applied indications. Committee also recommended to revise prescribing information of Esomeprazole Gastro Resistant capsules IP 40 mg in-line with the innovator's reference product