Recommendations of the SEC (Gastroenterology & Hepatology) made in its 07th/24 meeting held on 25.07.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/97/23 Online Submission (33453) Efruxifermin	M/s. KlinEra Global	The firm presented protocol amendment 1 dated 09.11.2023 protocol No. AK-US-001-0107. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/81/24 Online Submission (43829) AVT16 (INN: Vedolizumab)	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical trail protocol no. AVT16-GL-C01 version 3.0 (protocol amendment 2.0) dated 02.02.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.
Biological Division			
3.	BIO/CT04/FF/2024/42511 Vedolizumab powder for concentrate for solution for infusion 300 mg/vial	M/s. Intas Pharmaceuticals Ltd.	The firm presented the proposal for grant of permission to conduct Phase III clinical trial as per protocol titled "A Phase III, Randomized, Double-Blind, Multicenter, Active-Controlled, Two-Arm, Parallel Group Study to compare the Efficacy, Safety, Immunogenicity and Pharmacokinetics of the Proposed Biosimilar of Vedolizumab (INTP53) Intravenous Injection and Vedolizumab Reference for Induction and Maintenance Therapy in Patients with Moderate to Severe Active Ulcerative Colitis" vide protocol number: 0046-24 Version No. 1.0, Dated 23-02-2024. After detailed deliberation, the committee recommended to conduct Phase III clinical trial as per the protocol presented by firm.
4.	BIO/CT21/BO/2023/39673 Adalimumab solution	M/s. Shilpa Biologicals Private Limited	In light of the earlier SEC recommendation dated 30.04.2024, the proposal of the firm has been redeliberated for approval of following

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	for injection 40 mg/0.4 ml		additional indications by the way of extrapolation in line with the indications of innovator product: 1. Crohn's disease 2. Ulcerative colitis 3. Paediatric Crohn's disease 4. Paediatric ulcerative colitis. After detailed deliberation, the committee recommended for approval of the proposed additional indications 1. Crohn's disease 2. Ulcerative colitis in adults only. Further, the committee recommended to submit the PSUR data generated for the above indications in adults for consideration of approval in Paediatric group.
SND Division			
5.	SND/MA/23/000215 Ademetionine 1,4-butanedisulfonate 500mg lyophilized powder for solution for injection	M/s. La-Renon Healthcare Private Limited	In light of earlier SEC recommendation dated 30.04.2024, firm has presented the phase III clinical trial protocol no. CT/202426 version No.00 dated 01.05.2024 before the committee. After detailed deliberation, committee recommended for grant of Clinical Trial permission as per the protocol presented and submit the clinical trial report to the CDSCO further review by the committee.
New Drugs Division			
6.	ND/IMP/20/000032 Sodium Glycerophosphate 4.32 g/20 ml Concentrated Solution for Infusion	M/s. Fresenius Kabi	Under discussion with division.
7.	ND/IMP/23/000054 Carbon-14 urea 37Kbq Capsules (PY test capsules)	M/s. 3BMS Diagnostics Pvt. Ltd.	Firm presented the phase III clinical trial protocol of new drug Carbon-14 urea 37Kbq Capsules (PY test capsules) before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct phase III clinical trial as per the protocol presented.
8.	ND/MA/24/000085 Fexuprazan	M/s. Sun Pharmaceutical	The firm presented their proposal for grant of permission to manufacture and

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	Hydrochloride tablets 40mg	Industries Ltd.	market Fexuprazan Hydrochloride tablets 40 mg indicated for the treatment of Erosive Esophagitis (EE) along with the Bioequivalence study protocol vide protocol No. 052/23 Version-00, Dated: 22.01.2024, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the bioequivalence study as per the protocol presented by the firm.
FDC Division			
9.	FDC/MA/19/000089 Sodium Alginate IP 250mg + Sodium Bicarbonate IP 133.5mg + Calcium Carbonate IP 80mg per 5mL Oral liquid	M/s. Naxpar Pharma Pvt. Ltd.	In light of earlier SEC recommendation dated 13.03.2024 and 20.06.2024, the firm presented the source data of the Active PMS report before the committee. After detailed deliberation, the committee noted and agreed to the result of the Active PMS report.