Recommendations of the SEC (Gastroenterology & Hepatology) made in its 4th/24 meeting held on 30.04.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/138/22 Online Submission (31539) Tegoprazan	M/s. Dr. Reddy's	The firm presented the proposal to increase the number of subjects from 178 to 195 vide approved protocol No. 4.1 dated 01 March 2024 protocol number DRL-IND-NDA08-TEG/2022. After detailed deliberation, the committee recommended for approval of protocol amendment and increase in number of subjects from 178 to 195 as presented by the firm.
2.	CT/106/22 Online Submission (31778) Bepirovirsen	M/s. GSK Pharma	The firm presented protocol amendment version 3 dated 06 Feb 2024 protocol number 202009. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/107/22 Online Submission (31903) Bepirovirsen	M/s. GSK Pharma	The firm presented protocol amendment version 03 dated 09 Feb 2024 protocol number 219288. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/164/22 Online Submission (29876) Oral Ozanimod	M/s. PSI CRO	The firm presented the proposal to increase the number of patients from 10 to 30 vide approved protocol No.: RPC01-3203, protocol version 6.0 dated 14/06/2021. After detailed deliberation, the committee recommended for approval to increase the number of patients from 10 to 30, subject to condition that data safety monitoring board report (DSMB) should be submit to CDSCO.
Biological Division			
5.	BIO/CT21/BO/2023/39673 Adalimumab 40 mg/0.4 ml solution for	M/s. Shilpa Biologicals Private Limited	The firm presented the proposal for approval of following additional indications by the way of extrapolation in line with the indications of innovator product : 1. Crohn's disease 2. Ulcerative

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	injection		colitis 3. Paediatric Crohn's disease 4. Paediatric ulcerative colitis. After detailed deliberation, the committee recommended the firm to present the proposal in detail along with proper justification on additional indications for further deliberation before the committee.
SND Division			
6.	SND/MA/23/000163 Esomeprazole Delayed Release Oral Suspension 10mg	M/s. Dr. Reddy's Labs Limited	In light of earlier SEC recommendations dated 16.01.2024 & 17.01.2024, the firm presented bioequivalence study protocol (protocol No. 23-125 version No.01 dated: 28.12.2023) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct bioequivalence study as per protocol presented by the firm.
7.	SND/MA/23/000215 Ademetionine-1,4-butanedisulfonate 500mg lyophilized powder for injection	M/s. La-Renon Healthcare Private Limited	In light of earlier SEC recommendations dated 16.01.2024 & 17.01.2024, the firm again presented justification for clinical trial waiver including global clinical safety & efficacy data, Italian and Russian study data for waiver of Phase-III clinical trial before the committee. The committee noted that firm has not provided clinical safety & efficacy data on Indian patient/population. After detailed deliberation, the committee Reiterated with earlier SEC recommendation that the firm should conduct Phase-III clinical trial for which protocol to be submit to CDSCO for further review by the committee.
New Drugs Division			
8.	ND/MA/24/000010 Upadacitinib Extended- Release Tablets 15mg, 30mg, and 45mg	M/s. Optimus Pharma Pvt. Ltd.	The firm presented the proposal for grant of permission to conduct BE study and Phase III clinical trial study to manufacture and market drug Upadacitinib extended release tablets 15mg, 30mg & 45mg before committee. After detailed deliberation, the committee recommended for grant permission to conduct the BE study as per the protocol

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			presented. Further, the committee opined that firm should submit the rationale for Open Label study in Phase III clinical trial protocol and BE study reports to CDSCO for further deliberation.
9.	ND/IMP/23/000087 Etrasimod Tablets 2mg	M/s.Pfizer Product India Pvt.Ltd.	The firm didn't turn up for presentation.
FDC Division			
10.	FDC/MA/23/000345 Apremilast IP 15mg/25mg + Rifaximin 500mg/500mg film coated tablet	M/s. Zydus Lifesciences Limited	The firm presented proposal before the committee. The committee noted that the individual strength of the drug in the proposed FDC is not approved by CDSCO. After detailed deliberation, committee opined the following: 1. The firm did not present the rationality of the combination in proposed strength and its significant benefits. 2. The firm did not present any published literature in support of proposed strength and indication of the proposed FDC. 3. The firm did not present any published literature/data in support of individual unapproved drug strength or its concomitant use. Accordingly, the firm should submit above data for further review by the committee.