Recommendations of the SEC (Gastroenterology &Hepatology)made in its 68th meeting held on 13.12.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000130 Uplacitinib Extended Release Tablets 15 mg/ 30mg / 45mg	M/s. MSN Lab Pvt. Ltd.	The firm presented their proposal for grant of permission to conduct Phase III clinical trial to manufacture and market drug Upadacitinib extended release tablets 15mg, 30mg & 45mg along with bioequivalence study report of both fed and fasting condition before committee. After detailed deliberation, the committee recommended for grant permission to conduct the Phase III clinical trial with drug Upadacitinib extended release tablets 15mg, 30mg & 45mg as per the protocol presented subject to the condition that firm should include QuantiFERON-TB Gold test for exclusion of latent Tb cases.
2.	ND/CT/23/000079 Fexuprazan Hydrochloride Tablets 40 mg	M/s. Sun Pharmaceuticals Laboratories	The firm presented their proposal for grant of permission to conduct Phase III clinical trial to import and market drug Fexuprazan Hydrochloride Tablets 40 mg. After detailed deliberation, the committee recommended for grant permission to conduct the Phase III clinical trial with Fexuprazan Hydrochloride Tablets 40 mg as per the protocol presented subject to the condition that trial sites should be geographically distributed with 50% of Govt. institutes throughout the country and Principal Investigator as G.I. surgeon should not be included for the study.
Biological Division			
3.	BIO/CT21/FF/2023/39520 Golimumab Solution for Injection 50mg and 100mg	M/s. Reliance Life Sciences	The firm presented the proposal for approval of additional indication of Ulcerative Colitis for the drug Golimumab solution for injection 50mg and 100mg by the way of extrapolation in line with the indication of innovator drug. After detailed deliberation, the committee recommended for approval of proposed additional indication Ulcerative Colitis in line with the indications of innovator

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			drug with condition to conduct Phase IV clinical trial for establishing safety and effectiveness. Effectiveness of the drug shall be assessed by induction dosing and assessing clinical remission/response and endoscopic remission/response.
4.	BIO/CT21/FF/2023/39464 Ustekinumab Injection45mg/0.5ml and 90mg/mL	M/s. Reliance Life Sciences	The firm presented the proposal for approval of indications of Crohn's Disease and Ulcerative Colitis for drug Ustekinumab solution for Injection (45 mg/0.5ml & 90 mg/ml in PFS) by the way of extrapolation in line with the approved indications of innovator drug. After detailed deliberation, the committee recommended for approval of the proposed indications Crohn's Disease and Ulcerative Colitis in line with approved indications of innovator drug with a condition to conduct Phase-IV clinical trial for establishing safety and effectiveness. Effectiveness of the drug shall be assessed with induction dosing and assessing clinical remission/response and endoscopic remission/response and changes in Faecal Calprotectin levels. The proposed Phase IV clinical trial protocol shall include 1/3 of the subjects for the indication of Crohn's Disease and 2/3 of the subjects for the indication of Ulcerative Colitis.
FDC Division			
5.	FDC/MA/23/000345 Apremilast IP + Rifaximin (15mg + 500mg & 25mg + 500mg) film coated tablet	M/s. Zydus Lifesciences Limited	The firm didn`t turn up for presentation.
GCT Division			
6.	CT/124/23 Online Submission (39923) RVT-3101	M/s. Worldwide Clinical Trials	The firm presented Phase II clinical study protocol No. RVT-3101-201. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm
7.	CT/157/22 Online Submission (29817)	M/s. PSI CRO Pharma	The firm presented for 20 numbers of additional patients in India, protocol No. RPC01-3201. After detailed deliberation, the committee

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	Ozanimod Capsules		recommended for approval of the20 additional patients in the trial in India as presented by the firm.
8.	CT/127/20 Online Submission (29689) Semaglutide	M/s. Novo Nordisk India Pvt. Ltd	The firm presented protocol amendment version 14.0 dated 25 September 2023, protocol No. NN9931-4553. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
9.	CT/87/22 Online Submission (28837) VTX002	M/s. PSI CRO Pharma Pvt. Ltd	The firm presented protocol amendment version 5.0 dated 09 May 2023 and version 6.0 dated 21st July 2023, protocol No. VTX002-201. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
10.	CT164/22 Online Submission (29876) Ozanimod	M/s. PSI CRO	The firm didn't turn up for Presentation
11.	CT/43/19 Online Submission (29867) Mirikizumab	M/s. Eli Lilly	The firm presented protocol amendment (e) dated 31 October 2023 and protocol addendum (17.3) dated 31 October 2023 protocol No. 16-MC-AMAP. After detailed deliberation, the committee recommended for approval of the protocol amendment and addendum(17.3) as presented by the firm
BA/BE Division			
12.	File No. 12-09/2023/BA-BE/MISC-35/DC (BABE/CT05/FF/2023/39215) Rabeprazole Sodium Modified Release Capsules 40 mg	M/s. Dr. Reddy's Laboratories Limited, Telangana	The firm presented their proposal along with the BE Study protocol for Export purpose. After details deliberation the committee recommended for conducting the BE study (for export purpose only) of Rabeprazole Sodium Modified Release Capsules 40 mg as per the submitted Protocol.