Recommendations of the SEC (Gastroenterology & Hepatology) made in its 67th meeting held on 21.11.2023 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 has submitted the revised protocol no.MSN/CT/Upada/2023-2024, version1.1, dated on 20.11.2023 through e-vartalap. Hence, the proposal may be deliberated after technical review of the said protocol.
SND Division			
2.	SND/MA/23/000212 Rebamipide Tablets 100mg (Additional Indication)	M/s. Macleods Pharmaceuticals Limited	The firm presented the published literature and Clinical trial protocol for the additional indication for the Rebamipide Tablets 100mg for treatment of Post-banding Variceal ulcers in patients Undergoing Endoscopic Variceal Ligation (EVL). After detailed deliberation, the committee recommended to include control group of placebo in the study design, the sample size to be increased, to mention the specific indication of EVL, to include inclusion criteria clearly and to change the primacy efficacy end point. The firm should submit the revised protocol for further deliberation by the committee. The Committee also recommended removal of term gastroprotective from trial title as post EVL ulcer are in esophagus.
3.	SND/MA/21/000089 Omeprazole Delayed Release Orally Disintegrating Tablet 20 mg	M/s. Dr. Reddy's Labs Limited	The firm presented the proposal for manufacture and marketing of drug Omeprazole Delayed Release Orally Disintegrating Tablet 20 mg before the committee along with bioequivalence study report. After detailed deliberation, the committee recommended for grant of permission to manufacture & market the drug Omeprazole Delayed Release Orally Disintegrating Tablet 20 mg. However, the firm is required to comply with the requirement of CMC data.
FDC Division			

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4.	FDC/MA/19/000015 Levosulpiride (as uncoated sustained release tablet) 75 mg +Rabeprazole Sodium IP (as gastro resistant form) 40 mg hard gelatin capsule	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 17.01.2023, the firm presented their proposal along with BE report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC, subject to condition that the firm should conduct Active PMS study. Accordingly, the firm should submit Active PMS study protocol to CDSCO within 03 months of approval for review by the committee.
GCT Division			
5.	CT/107/22 Online Submission (27229) GSK3228836 Solution for Injection 150 mg/mL (Bepirovirsen)	M/s. GSK Pharma	The firm has presented protocol amendment version 01 dated 20 March 2023, Protocol no. 219288. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
6.	CT/105/23 Online Submission (39332) JNJ-77242113	M/s. Johnson & Johnson	The firm presented phase 2b clinical trial, protocol no. 77242113UCO2001. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more geographically distributed sites shall be included in the study.
7.	CT/125/22 Online Submission (28116) MORF-057	M/s. PSI CRO Pharma	The firm presented protocol amendment version 2.0 dated 26 April 2023 and increase in number of subjects in India from 19 to 60 in number in Protocol no. MORE-057-202. After detailed deliberation, the committee recommended for approval of the protocol amendment and increase in number of subjects in India from 19 to 60 as presented by the firm
8.	CT/139/22 Online Submission (28205) Guselkumab and Golimumab	M/s. Parexel	The firm presented protocol amendment 02 dated 11 Jan 2023, amendment 03 dated 29 –June 2023 Protocol no. COMB157G2399. After detailed deliberation, the committee recommended for approval of the

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			protocol amendment as presented by the firm with condition that more government sites (approx 40 to 50%) should be included in the study.
9.	CT/140/22 Online Submission (28206) Guselkumab and Golimumab	M/s. Parexel	The firm presented protocol amendment 02 dated 11 Jan 2023, amendment 03 dated 29 –June 2023 Protocol no. 78934804UCO2001. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm with condition that more government sites (approx 40 to 50 %) should be included in the study.
10.	CT/142/22 Online Submission (28502) AZD2693	M/s. AstraZeneca	The firm presented protocol amendment version 3.0 dated 04 August 2023, Protocol no. D7830C00004. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
11.	CT/18/20 Online Submission (28675) Hydrocortisone Acetate 90 mg	M/s. Novotech	The firm has presented protocol amendment version 4.0 dated 08 September 2023, Protocol no. CHS1221. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
12.	CT/79/23 Online Submission (38193) Pantoprazole Sodium 5mg, 10mg, 20 mg & 40 mg (PF-05208751)	M/s. Pfizer	In light of earlier SEC recommendation dated 14.09.23, the firm presented phase IIb clinical study protocol no. B1791094. After detailed deliberation, the committee recommended that the proposal should be re-deliberated in presence of bigger panel of 5 members including at least 3 paediatric gastroenterologists.
13.	CT/125/23 Online Submission (39965) Ambrisentan	M/s. Nextvel Consulting LLP	The firm presented phase II clinical trial, protocol no. N-003-CRD005. After detailed deliberation, the committee recommended to grant of permission to conduct the trial as presented by the firm.