Recommendations of the SEC (Gastroenterology &Hepatology) made in its 1st/24 meeting held on 16.01.2024&17.01.2024 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCTDivision			
1.	CT/79/23 Online Submission (38193) Dated 26/06/2023 Pantoprazole Sodium (PF-05208751) delayed release capsules, 5mg, 10mg, 20mg and 40mg	M/s. Pfizer Limited	In light of earlier SEC the proposal was deliberated in SEC on 21.11.23, the firm presented Phase IIb clinical study protocol No. B1791094. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with condition that: 1. All 3 endoscopies shall be conducted in single center only by paediatric gastroenterologist. 2. Academic institute having tertiary care facilities shall be included in the study.
2.	CT/165/22 Online Submission (30047) Dated 08/12/2023 Ozanimod Capsules	M/s. PSI CRO Pharma Pvt. Ltd.	The firm presented protocol amendment 6.0 dated 16 March 2023, protocol No. RPC01-3204. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
3.	CT/181/22 Online Submission (30210) Dated 19/12/2023 ABX464 (Obefazimod)	M/s. IQVIA RDS (India) Private Limited	The firm presented protocol amendment version 4.1 dated 03 November 2023 and increase in number of subjects from India protocol No. ABX464-105 After detailed deliberation, the committee recommended for approval of the protocol amendment and enrolling additional 22 numbers of subjects as presented by the firm.
4.	CT/05/23 Online Submission (30353) Dated 22/12/2023 ABX464 (Obefazimod)	M/s. IQVIA RDS (India) Private Limited	The firm presented protocol amendment version 4.1 dated 03 November 2023 and increase in number of subjects from India protocol No. ABX464-106 After detailed deliberation, the committee recommended for approval of the protocol amendment and enrolling additional 10 numbers of subjects as presented by the firm.
5.	CT/106/22 Online Submission (27228) Dated 13/07/2023 GSK3228836	M/s GSK Pharma India Private Limited	In light of the earlier recommendations of SEC held on 17.10.2023, the firm presented justification and protocol No. 202009, amendment version 01 dated 20 March 2023 before the committee.

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	Solution for Injection 150 mg/mL (Bepirovirsen)		After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
6.	CT/164/22 Online Submission (29876) Dated 30/11/2023 Oral Ozanimod	M/s. PSI CRO	The firm did not turn up for presentation.
Biological Division			
7.	BIO/CT04/FF/2023/37764 Ustekinumab injection 45mg/0.5ml	M/s Biocon	The firm did not turn up for presentation.
SND Division			
8.	SND/MA/23/000215 Ademetionine 1, 4-Butane disulfonate injection 500mg/vial	M/s La Renon Healthcare pvt ltd	The firm presented their proposal for grant of permission to manufacture and marketing of Ademetionine 1, 4- Butane disulfonate injection 500mg/vial (Additional Strength, Dosage form & indication) along with justification for waiver of Phase-III clinical trial before the committee. The firm has informed that Ademetionine injection 500mg/ml is already approved in France, Lithuania, Bulgaria, Belarus, and Armenia, Krygyzstan, Uzbekistan and China for the treatment of depression, liver disorders, fibromyalgia and osteoarthritis. Further, Ademetionine enteric coated tablets 200mg/400mg is approved on 01.09.2010 in India for the management of intrahepatic cholestasis and liver disease. After detailed deliberation, the committee noted that the justification provided by the firm for waiver of clinical trial in not found adequate. Therefore, the committee recommended to conduct Phase-III clinical trial for which the firm should submit clinical trial protocol to CDSCO for further review by the committee.

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9.	SND/MA/23/000163 Esomeprazole Magnesium Delayed Release Oral Suspension10mg	M/s. Dr. Reddy`s Laboratories Limited	In earlier SEC meeting dated 17.10.2023, their proposal for Esomeprazole Magnesium delayed release oral suspension 10mg, 20mg and 40mg along with bioequivalence study report of Esomeprazole Magnesium delayed release oral suspension 40mg was deliberated for which the committee requested **the** firm to present the relevance of the proposed oral suspension in Indian population. and committee recommended to conduct Phase-III clinical trial. The firm proposed only one strength i.e. Esomeprazole Magnesium delayed release oral suspension10mg along with Justification for waiver of clinical trial before the committee. After detailed deliberation, the committee recommended that the firm should conduct bioequivalence study of Esomeprazole Magnesium delayed release oral suspension 10mg for which the firm should submit bioequivalence study protocol to CDSCO for further review by the Committee.
10.	SND/CT/23/000066 Ursodeoxycholic Acid 625mg/25ml (25mg/ml) intravenous injection	M/s Shilpa Medicare Limited	In light of earlier SEC recommendations dated 26.10.2023, the firm presented the Phase-II/III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-II clinical trial of Ursodeoxycholic Acid 625mg/25ml (25mg/ml) intravenous injection and submit report to CDSCO for further consideration of Phase-III clinical trial by the committee.
New Drug Division			
11.	ND/MA/23/000123 Vonoprazanfumarate Tablets 10 mg and 20 mg	M/s Synokem Pharmaceuticals Ltd.	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Vonoprazan tablets 10mg/20mg along with Phase III clinical trial protocol and BE study waiver before the committee.

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			After detailed deliberation, the committee agreed for waiver of BE study and recommended for the grant of permission to conduct proposed Phase-III clinical trial as per the protocol presented subject to satisfactory evaluation of dissolution data by CDSCO.
12.	ND/MA/23/000133 Linaclotide capsules 145 mcg & 290 mcg	M/s. Aurbindo Pharma	The firm has submitted proposal to manufacture and market Linaclotide capsules 145 mcg and 290 mcg in the country along with Phase-III clinical end-point study report of Linaclotide 290 mcg conducted in the country. After, detailed deliberation, the committee recommended for the manufacturing and marketing permission of Linaclotide 290mcg capsules indicated in adults for the treatment of irritable bowel syndrome with constipation (IBS C). The firm should submit the post marketing surveillance data of other countries where the drug is marketed to CDSCO. The firm should submit the Phase-III clinical trial protocol for the Linaclotide145mcg for evaluation in the Indian population.
13.	ND/MA/22/000191 Vonoprazan Tablets 10mg & 20mg	M/s. Hetero Labs Limited	In light of earlier SEC recommendation dated 17.01.2023, the firm has presented Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the drug Vonoprazan tablets 10mg/20mg with the condition that the firm should conduct Phase IV clinical trial for which the protocol should be submitted within 3 months of approval of the drug for review by the committee.
FDC Division			
14.	FDC/MA/24/000005 Domperidone Maleate IP eq. to Domperidone (10mg as immediate release and 20mg as sustained	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm presented their proposal before the committee. The committee noted that the FDC Pantoprazole 40mg EC + Domperidone 30mg SR capsules indicated for the treatment of GERD not responding to

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	release) 30mg + Pantaprazole sodium Ip eq. to Pantaprazole (As delayed release tablet) 40mg uncoated bilayered tablet		pantoprazole has been approved by this office on 18.05.2005. However, the applied FDC is in tablet dosage form. After detailed deliberation, the committee opined that firm should present in-vitro study data from accredited approved laboratory for further review by the committee.