Recommendations of the SEC (Gastroenterology & Hepatology) made in its 11th meeting held on 14.11.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/CT04/FF/2024/45173 Online Submission (45173) RO7790121	M/s Roche	The firm presented phase 3 clinical study protocol no. GA45329 version 2 dated 30 April 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that uniformity with respect to screening of tuberculosis shall be maintained at each site.
2.	GCT/PostAppr/2024/35267 Online Submission (35267) PB016 (Vedolizumab)	M/s Worldwide	The firm presented protocol amendment version 2.1 dated 16 September 2024 and Increase the number of randomized patients in India by 100 (in total 350) protocol no. PB016-03-01. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm and increase in number of subjects by 100 (in total 350).
3.	GCT/CT04/FF/2024/45175 Online Submission (45175) RO7790121	M/s Roche	The firm presented phase 3 clinical study protocol no. GA45330 version 2 dated 30 April 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that condition that uniformity with respect to screening of tuberculosis shall be maintained at each site.
SND Division			
4.	SND/MA/20/000083 Ursodeoxycholic acid IP 150mg/300mg/ 450mg/600mg Tablet	M/s. Abbott Healthcare Pvt. ltd	In light of the earlier SEC recommendations dated 17.06.2021, the firm has presented the clinical study report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Ursodeoxycholic acid IP 300mg/450mg tablets as the firm has conducted the clinical study with 300mg/450mg tablets for the treatment of Obstetric Cholestasis

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			(Intrahepatic Cholestasis of pregnancy) with a condition that firm should conduct Post marketing surveillance (PMS) study. Accordingly, the firm should submit PMS study protocol to CDSCO within 03 months from date of approval of the drug for further review by the SEC Committee.
5.	SND/MA/23/000189 Sodium Picosulfate Oral Solution BP 2.5mg/5ml	M/s. Pharma Force Lab	In light of the earlier SEC recommendations dated 15.02.2024, the firm has presented the review articles and published clinical data on Indian and other population. After detailed deliberation, the committee opined that firm could not provide the relevant clinical trial data/PMS data on Indian population. Hence, the committee reiterated its earlier recommendation that firm shall provide either the published clinical data on Indian population (adult & children of 12 years of age) or submit the Phase III clinical trial protocol for further review.
6.	SND/MA/23/000163 Esomeprazole Magnesium for Delayed Release Oral Suspension 10 mg	M/s. Dr. Reddy's Laboratories Limited	In light of the earlier SEC recommendations dated 30.04.2024, the firm has presented the Bioequivalence study report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and market of Esomeprazole Magnesium for Delayed Release Oral Suspension 10 mg for the applied indication.
New Drugs Division			
7.	ND/IMP/24/000037 Tegoprazan Tablet 50 mg	M/s Dr Reddys Laboratories Limited	The firm presented the proposal of grant of permission to import and market of new drug Tegoprazan tablet 50 and 25 mg along with PK study report and Phase III Global clinical trial study report before the committee. After detailed deliberation, the committee noted that the firm has completed Phase III Global clinical trial study and India is one of the participating country in the said Phase III Global CT study. Accordingly, the committee recommended for the grant of permission to import and market of new drug
8.	ND/IMP/24/000070 Tegoprazan Tablet 25 mg	M/s Dr Reddys Laboratories Limited	

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			Tegoprazan Tablet 50 mg for the following indication:- 1. Erosive Gastroesophageal Reflux Disease 2. Non erosive Gastroesophageal Reflux Disease 3. Gastric ulcer and the grant of permission to import and market of new drug Tegoprazan Tablet 25 mg for the following indication:- 1. Maintenance of healed Erosive Gastroesophageal Reflux Disease Further, the committee also recommended that for the indication w.r.t. adjuvant to H. pylori in combination with antibiotics, the firm is required to conduct phase III clinical trial in Indian population as the global data on H. pylori treatment with Tegoprazan is limited and resistance pattern are different across the countries.