Recommendations of the SEC (Gastroenterology & Hepatology) made in its 04th/25 meeting held on 23.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	r-DNA-11016(13)/6/2025-eoffice Vedolizumab 300mg IV	M/s Takeda Biopharmaceuticals India Pvt Ltd	The firm did not turn up for the presentation.
New Drugs Division			
2.	P-29010/17/2025-DMCell Rectal indomethacin and oral tacrolimus	Department of Gastroenterology & HNU, AIIMS, New Delhi	The study investigator, Department of Gastroenterology & HNU, AIIMS, New Delhi presented protocol titled "A randomized trial comparing rectal indomethacin alone versus a combination of rectal indomethacin and oral tacrolimus for post-ERCP pancreatitis prophylaxis" for the conduct of clinical trial with the drug Rectal indomethacin and oral tacrolimus. After detailed deliberation, the committee recommended for the grant of permission to conduct the clinical trial as per the protocol presented.
3.	ND/MA/25/000033 Resmetirom Tablets 60mg, 80mg & 100mg	M/s Torrent Pharmaceutical Ltd.	The firm has presented the proposal for grant of permission to manufacture and market of Resmetirom Tablets 60mg/ 80 mg /100 mg along with BE study report and Phase III Clinical Trial Protocol before the committee. After detailed deliberation, the committee considered the BE study results of Resmetirom Tablets and recommended for grant of permission to conduct Phase III clinical trial.
SND Division			
4.	SND/CT/25/000001 Rabeprazole Sodium Oral Disintegrating Tablet (ODT) 20mg	Dr. Reddy's Laboratories Limited	The firm has presented the proposal for the grant of permission to conduct Phase-IV clinical trial of Rabeprazole Sodium Oral Disintegrating Tablets (ODT) 20 mg. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-IV clinical trial as per the protocol presented by the firm with

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			the following changes in the protocol 1. Firm should remove the word "Observational" from the title of the protocol. Accordingly, firm shall submit the revised protocol to the CDSCO
FDC Division			
5.	FDC/MA/24/000106 Combikit of Clarithromycin IP 500mg film coated tablet + AmoxycillinTrihydrate IP eq. to Amoxycillin 1000mg film coated tablet + Pantoprazole Sodium IP 40mg Enteric coated tablet	M/s Malik Lifesciences Pvt. Ltd.	In light of earlier SEC recommendation Dated 20.06.2024, the firm presented their proposal along with BE protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, the firm should submit BE study report to CDSCO for further review by the committee.
6.	FDC/MA/23/000079 Each Chewable Tablet Contains:Famotidine IP 10 mg + Calcium carbonate IP 800 mg + Magnesium hydroxide IP165 mg.	M/s PURE & CURE HEALTHCARE Pvt. Ltd	In light of earlier SEC recommendation Dated 20.12.2024, the firm presented the proposal along with revised Active PMS protocol before the committee. After detailed deliberation, the committee recommended for conducting the Active PMS study with the following conditions that should be included in the Active PMS protocol: 1. Surveillance of serum calcium and magnesium level before and after the study and at regular intervals. 2. ECG surveillance should be included in the protocol for 6 months. 3. To access the number of hours of symptoms relief. Accordingly, the revised Active PMS protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Active PMS study report for further review by the committee.