Recommendations of the SEC (Gastroenterology & Hepatology) made in its 64th meeting held on 14.09.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/IMP/20/000021 Mesalazine tablets 500mg	M/s. Ferring Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for updation in package insert (PI) to include following updation: 1. Addition in method of administration for use with Yogurt for PENTASA granules 1g and 2g. 2. Update of package inserts of PENTASA tablet (Mesalazine 500mg prolonged released tablets), granules (Mesalazine prolonged released granules 1g) , Mesalazine prolonged released granules 2g) and suppositories (Mesalazine suppositories 1g) due to PRAC recommendation before the committee. The firm informed that they are already holding the marketing authorization for Mesalazine 500mg (prolonged released tablets), Mesalazine prolonged released granules 1g, mesalazine prolonged released granules 2g & Mesalazine suppositories 1g. The Committee noted that the Pentasa granules administration with yogurt is also approved in several countries including Switzerland (country of origin), Germany, Australia, the Czech Republic, Denmark. After detailed deliberation, the committee recommended for updation of the method of administration of Mesalazine prolonged release granules 1g & 2g for use with Yogurt. However, the firm should submit approved package insert from the country of origin with the proposed changes like urine discoloration, skin subcutaneous disorders etc to CDSCO for further review by the committee.

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GCT Division			
2.	CT/75/23 Online Submission (37851) Efruxifermin	M/s. Klinera	The firm didn`t turn up for presentation.
3.	CT/79/23 Online Submission (38193) Pantoprazole Sodium (PF05208751)delayed release capsules, 5mg, 10mg, 20mg and 40mg	M/s. Pfizer Limited	The firm presented Phase IIb clinical study protocol No. B1791094, protocol amendment 3 final 06 October 2022. After detailed deliberation, the committee opined that the proposal should be re-deliberated in presence of paediatric gastroenterologist and following should be presented by the firm. 1. Symptom duration before screening. 2. Indication for endoscopy as per current guidelines. 3. Evidence for availability of paediatric gastroenterologist and gastroenterologist having experience in performing paediatric endoscopy. 4. More Government sites to be included in the trial.
Medical Device Division			
4.	IMP/MD/2023/81256 Faciotens Abdomen, Fasiotens Hernia, Fasiotens Paediatric	M/s. Olivine International	The firm presented their proposal for grant of permission to import medical device which does not have predicate medical device before the committee. After detailed deliberation, the committee recommended as under: 1. The firm need to include global regulatory approval details along with sales/ marketing data in their presentation. 2. The firm should submit more clinical data to demonstrate safety and efficacy of the product Fasciotens Paediatric. Accordingly, the firm should submit the documents and the proposal should be re-deliberated in the next SEC meeting.
5.	CI/MD/2023/94424 EBDLR System	M/s. Ardent Clinical Research Services	The firm presented the proposal for conduct of clinical investigation of the proposed product Extracorporeal Bioengineered Dual-Cell Liver

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			Regeneration System (EBDLR) before the committee as per protocol No: 001/EBDLR/YLSPLT/2023, version 1.1 dated 12May, 2023. After detailed deliberation, the committee recommended as under: 1. To modify the inclusion and exclusion criteria. 2. To specify the centres where the study will be conducted, considering that 50% of the study site should be government hospital/ institutions. Accordingly, the firm should revise the clinical investigation plan and submit the same for re-deliberation in the next SEC meeting.