Recommendations of the SEC (Gastroenterology & Hepatology) made in its 43rd meeting held on 17.12.2021at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	Ranitidine	Recommendation of SRP of PvPI	The recommendation of the SRP of PvPI, IPC was deliberated before the committee. The committee noted that, SRP after critical evaluation of the ADR concluded that the causal relationship between intravenous ranitidine and cardiac arrest can be established but no association can be established with effervescent tablet with available data. Product labeling information also refer that as with other H2 receptor antagonists bradycardia, AV block with injection only was mentioned in the package insert of Ranitidine IV marketed in UK. After detailed deliberation, the committee recommended that CDSCO should request State Drugs Controllers to direct the manufacturers of the drug that same label should be incorporated in the package insert of Ranitidine IV product marketed in India. However, the committee also requested CDSCO to share the details received from PvPI, IPC to the experts.
2.	ND/MA/21/000105 Sporlac 300 MCC tablets Probiotics	M/s.Sanzyme Private Limited	In light of earlier SEC recommendation dated 16.09.2021, the firm presented their justification before the committee. After detailed deliberation, the committee noted that there is no rationale for the proposed strength Sporlac 300 MCC probiotics tablets. Since, the firm is proposing higher strength for same indication, the firm needs to clarify if the proposed product is marketed as OTC or prescription drug in other countries. Accordingly, the firm should submit above information to CDSCO for further consideration.

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3.	ND/MA/21/000109 Sporlac 500 MCC tablets Probiotics	M/s.Sanzyme Private Limited	In light of earlier SEC recommendation dated 16.09.2021, the firm presented their justification before the committee. After detailed deliberation, the committee opined that the firm needs to clarify whether the proposed product is marketed as OTC or prescription drug in other countries. Accordingly, the firm should submit above information to CDSCO for further consideration.
Biological Division			
4.	BIO/CT18/FF/2021/28468 Vedolizumab	M/s.Takeda Pharmaceuticals	The firm presented their proposal for import and marketing of additional strength and new route of administration of Vedolizumab. The committee noted that Vedolizumab through IV route is already approved for marketing in the country. Further the proposed additional strength through subcutaneous route is approved in EU, Switerzland etc. After detailed deliberation, the committee recommended for grant of marketing permission of Vedolizumab of additional strength through subcutaneous route. Further, the indication should reflect that the additional strength is for subcutaneous route and only for maintenance purpose.
SND Division			
5.	SND/MA/21/000400 Pantoprazole Enteric Coated Delayed Release Tablet 40 mg	M/s.Lupin Limited	In light of SEC recommendation dated 16.09.2021, the firm presented the advantages and disadvantages of the proposed product over the existing formulation. After detailed deliberation, the committee recommended for conduct of the BE study as per the protocol presented earlier.
FDC Division			
6.	FDC/IMP/20/000088 Poloxamer 407 IH +	M/s. Micro labs Ltd	The firm presented their proposal before the committee along with justification for proposed sample size.

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	Sodium chondroitin sulphate IH + Sodium hyaluronate IH (2.7%+3.12%+1.24%) oral liquid		After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial with the revised sample size.
7.	FDC/MA/21/000224 Pantoprazole Sodium IP eq. to Pantoprazole +Acotiamide Hydrochloride trihydrate IP (as ER) IH (40mg+300mg) capsules	M/s. Akums Drugs and Pharmaceutical Ltd	The firm presented their proposal before the committee along with BE and CT protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. As regard to Phase III clinical trial protocol, the committee opined that- 1. The inclusion criteria should clearly mention about inclusion of NERD patients. Accordingly methodology for selection of such patients should also be mentioned. 2. Sample size appears to be low and should be justified. 3. Manometry as well as PH monitoring should be included in the study. 4. Exclusion criteria has to be relevant w.r.t the objective of the study. In view of above, the committee recommended that the firm should submit revised Phase III clinical trial protocol for further review by the committee.
GCT Division			
8.	CT/131/21OnlineSubmission(28532) BI685509	M/s. Parexel	In light of SEC recommendation dated 23.11.2021 the firm presented their justification before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study.
9.	CT/54/19OnlineSubmission(13300) Etrasimod	M/s. IQVIA	The firm presented their proposal for protocol amendment before the committee. After detailed deliberation, the committee recommended for approval of protocol amendment number APD334-303, version 3.0 dated 07-May- 2021 with following conditions :-

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			The firm needs to provide SoC in case of treatment failure and severe flare of disease including biologicals. The committee also suggested that the firm should include more government sites in the proposed trial.
10.	CT/49/20OnlineSubmission(13360) Mirikizumab	M/s. Eli Lilly	The firm presented their proposal for protocol amendment before the committee. After detailed deliberation, the committee recommended for approval of protocol amendment number I6T-MC-AMAM(c), dated 01-Apr- 2021 subject to following conditions :- 1) The firm should include equally distributed more government sites across India. 2) The firm needs to provide SoC in case of treatment failure and severe flare of disease including biologicals.
Medical Device Division			
11.	CI/MD/2021/50481 NOBIX System	M/s. CBCC Global Research LLP	The firm presented their proposal to conduct pilot clinical investigation before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed pilot clinical investigation in Indian patients subject to condition that before commercial use the firm has to conduct pivotal study in the country.
BA/BE Division			
12.	12-09/2021/BA-BE/Misc-28/DC Rifamycin Delayed- release Tablets 194mg	M/s. Cliantha Research Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended that the firm should include atleast 50% government sites and study should be conducted in reputed accredited hospitals spread across India.
13.	12-09/2021/BA-BE/MISC-24/DC AV104	M/s. CBCC Global Research LLP	The firm presented their proposal before the committee. After detailed deliberation, the

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			committee recommended that the firm does not have enough data to prove the safety of the test drug in the cirrhotic liver patients. Hence, animal data needs to be generated before conducting the proposed study.