Recommendations of the SEC (Analgesic & Rheumatology) made in its 88th meeting held on 13.09.2022 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-10/17-DC Remifentanil HCL 1mg & 2mg solution for Injection	M/s. Themis Medicare Ltd	In light of earlier SEC recommendation dated 18.05.2017, the firm presented Phase III clinical trial report. After detailed deliberation, the committee opined that the clinical data presented can be considered for grant of permission to manufacture and market the drug Remifentanil HCl 1mg & 2mg solution for injection. However, "there was one SAE (death) in one of the study subjects. The SAE report generated by the PI in the standard format has been reviewed by the committee. The opinion / comments /report of the local Institutional Ethics Committee regarding the causality of the SAE, with respect to patient monitoring of vitals until 11pm, concurrent medications before and after the infusion and Post mortem report to be reviewed by this committee for final recommendation in the matter."
2.	ND/MA/22/000115 Polmacoxib 2mg Capsule	M/s. Precise Biopharma Pvt. Ltd.	The firm presented their proposal along with Phase III clinical trial protocol and BE protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The firm should present the results of BE study before the committee for further consideration of Phase III CT protocol.
Biological Division			
3.	BIO/CT21/FF/2021/ 24679 Denosumab injection (60 mg/ml)	M/s. Reliance Life Sciences	In light of the SEC recommendation dated 27.07.2022, the firm presented Phase III clinical trial data with further statistical justification. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of the proposed drug subject to the condition that the firm should conduct Phase IV clinical trial in not less than 233 subjects in the country and should also include

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			subset of patients who have failed with Bisphosphonate therapy. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of marketing approval and advised that the firm should submit statistical analysis report certified by independent statistician.
4.	BIO/CT18/FF/2022/ 30484 Secukinumab 150mg/ml solution for injection in prefilled pen formulation	M/s. Novartis	The proposal was deferred for next meeting as per request of the firm.
SND Division			
5.	SND/MA/22/000239 Benzydamine Hydrochloride Mouthwash 0.15% w/v	M/s. Zuventus Healthcare	The firm presented their proposal for CT waiver for manufacture and marketing of the drug Benzydamine Hydrochloride Mouthwash 0.15% w/v before the committee. After detailed deliberation, the committee recommended that, the firm has not presented the data with respect to allergic reactions associated with the non - steroidal anti-inflammatory drug (NSAID). As the applied product is a local acting non-steroidal anti-inflammatory drug (NSAID), firm is required to submit the data of the allergic reaction associated with the applied product for its further review by the SEC.
GCT Division			
6.	CT/66/19 Online Submission (16807) Baricitinib	M/s. Eli Lilly	The applicant presented protocol amendment (Protocol: I4V-MC-JAHU(d) dated 18/02/2022 before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.
7.	CT/66/19 Online Submission (18330) Baricitinib	M/s. Eli Lilly	In light of CT-NOC conditions i.e. 1- For consideration of inclusion of pediatric patients aged 1 to 12 years, the firm should submit detailed supportive data of use of the drug in the pediatric age group (1-12 years) including justification for the proposed dose of the drug in light of the fact that as per regulatory provisions, the study should be conducted in children aged 12-18 years

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			before conducting the study in children aged 1-11 years. 2-The firm should submit all the data generated after conducting the study in 12-18 age group. Any permission to conduct the study in lower age group (< 12 years) will only be given after the above data is deliberated by the committee, the applicant presented safety and pharmacokinetic data of Baricitinibin age group 12-18 years before the committee. After detailed deliberation, the committee opined that the study should be continued in age group 12-18 years and more safety data needs to be generated globally and in Indian subjects and same data to be presented before the committee for further continuation of the trial in age group of less than 12 years.
8.	CT/124/21 Online Submission (18631) Tofacitinib	M/s. Pfizer	The applicant presented protocol amendment 6 dated 09/02/2022 before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment 6 dated 09/02/2022 with condition that re-screening should not be allowed for Indian subjects who failed during first screening.
9.	CT/67/22 Online Submission (33255) Tildrakizumab 100mg/ml	M/s. Sun Pharma	The firm presented their proposal for Phase III clinical trial protocol no. TILD-19-19 amendment 1.1 (India Specific) dated 04/07/2022 (Inspire 2) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with the following conditions- 1. Placebo arm should not be deprived of the standard of care (SOC). In placebo arm Methotrexate should be given as background therapy/SOC. 2. DSMB should be constituted and its recommendations should be submitted to CDSCO. 3. More Government sites should be included in the study.
10.	CT/68/22 Online Submission	M/s. Sun Pharma	The firm presented their proposal for Phase III clinical trial protocol no. TILD-

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	(33217) Tildrakizumab 100mg/ml		19-07 amendment 1.1 (India Specific) dated 04/07/2022 (Inspire 1) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with the following conditions- 1. Placebo arm should not be deprived of standard of care (SOC). In placebo arm Methotrexate should be given as background therapy/SoC. 2. Subject randomization will be stratified by body weight (≤ 90 kg and > 90 kg), disease activity and prior failed anti-TNF agents. 3. DSMB should be constituted and its recommendations should be submitted to CDSCO. 4. More Government sites should be included in the study.
Medical Device Division			
11	IMP/MD/2022/58425 NAV PAK Needle, Trocar and NIM NAV PAK Needle, Trocar International	M/s. India Medtronic Pvt. Ltd	The firm didn't turn up for presentation.
12	IMP/MD/2021/41651 INNOTERE 3D Scaffold	M/s. Avana Medical Devices Pvt. Ltd.	The firm didn't turn up for presentation.