Recommendations of the SEC (Analgesic & Rheumatology) made in its 04th/25 meeting held on 15.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/69/23 Online Submission (38861) Anifrolumab (MEDI-546)	M/s. AstraZeneca Pharma India Limited	The firm presented protocol amendment version 4.0 dated 28 Feb 2025 protocol no. D3460C00002. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with condition that value of FVC in secondary endpoint determined as unfavorable shall be defined.
2.	CT/120/23 Online Submission (38936) SAR441566 50 mg and 100 mg Tablet	M/s Sanofi Healthcare India Private Ltd.	The firm presented protocol amendment 05 version 01 dated 03 March 2025 protocol no. DRI17821. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/78/24 Online Submission (38988) VAY736 (Ianalumab)	M/s Novartis Healthcare Private Limited	The firm presented protocol amendment version 02 dated 28 Jan 2025 protocol no. CVAY736F12301E1. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with condition that the data generated on auto-injector (AI) device shall not be used for promotional purpose.
4.	CT/60/24 Online Submission (38976) Deucravacitinib	M/s Bristol-Myers Squibb India Pvt. Ltd.	The firm presented Protocol Amendment 03 dated 25 Jun 2024 protocol no. IM011-246. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/61/24 Online Submission (38989) Deucravacitinib	Bristol-Myers Squibb India Pvt. Ltd	The firm presented Protocol Amendment 03 dated 25 Jun 2024 protocol no. IM011-247. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
6.	E-54043 Denosumab solution for injection 120 mg/ 1.7 ml	M/s. Intas Pharmaceuticals Limited	The firm did not turn up for the presentation.
7.	BIO/CT04/FF/2025/48099 Abatacept solution for injection 125 mg/ mL PFS	M/s Syngene International Limited	The firm presented the clinical trial protocol to conduct Phase I clinical trial titled "A single-dose, randomized, open-label, parallel-group, comparative pharmacokinetic and safety study of subcutaneously administered abatacept biosimilar DRL_AB via autoinjector or pre-filled syringe in normal healthy male participants" for export purpose vide Protocol No, AB-01-007 version 1.0 dated 13.02.2025. After detailed deliberation the committee recommended for grant of permission to conduct the Phase I clinical trial as per the protocol presented by the firm.
SND Division			
8.	SND/MA/22/000079 Tofacitinib Sustained Release Tablets 11mg	M/s Mascot Health Series Pvt. Ltd	Firm presented Active PMS protocol no. MCR/CT/0225/01 ver. 00 dt. 10.02.2025 as per the condition mentioned in manufacturing and marketing permission dated 01.09.2022, before the committee. After detailed deliberation, the committee recommended for conducting the Active PMS study with condition to include atleast 25% patients for each indications. The result of the study should be submitted to CDSCO for review by the committee.
9.	SND/MA/24/000137 Paracetamol tablets 1000mg (IR)	M/s Alkem Labs Ltd	In continuation to the earlier SEC committee meeting dated 28.01.2025, the proposal for the approval of Paracetamol tablets IP 1000 mg for the indication "symptomatic relief of pain and fever in adults and elderly" was further deliberated in the SEC (Analgesic & Rheumatology) along with experts from Gastroenterology & Hepatology, Renal, Pharmacologist, General Physician and Toxicologist. After detailed deliberation, the committee opined that there is no rationality and medical need on the use of Paracetamol

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			Tablets IP 1000 mg for the applied indications and applied indications can be managed with the already approved formulations of Paracetamol. In view of the above, Committee did not recommended for the approval of the Paracetamol tablets IP 1000 mg for the applied indication.
FDC Division			
10.	FDC/MA/25/000076 Polmacoxib 2mg/2mg + Thiocolchicoside 4mg/8mg Capsules	M/s Hetero Labs Limited	The firm did not turn up for the presentation.