Recommendations of the SEC (Analgesic & Rheumatology) made in its 05th/25 meeting held on 24.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/143/24 Online Submission (39122) ESK-001	M/s Syneos Health India Pvt Ltd	The firm presented protocol amendment 2.0 version 5.0 dated 10 Feb 2025 protocol no. ESK-001-010. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/75/24 Online Submission (39250) VAY736 (Ianalumab)	M/s Novartis Healthcare Private Limited,	The firm presented protocol amendment version 01 dated 24 February 2025 CVAY736S12201. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Medical Devices Division			
3.	CI/MD/2023/95467 Cross linked Sodium Hyaluronate 88 mg with Triamcinolone Hexacetonide 18mg (Cingal)	M/s. Modi-Mundipharma Private Limited	The firm did not turn up for the presentation.
Biological Division			
4.	E-54043 Denosumab solution for injection 120 mg/1.7ml	M/s. Intas Pharmaceuticals Limited	The firm presented the final CSR of Phase I clinical trial titled "A Randomized, Double-Blind, Three-Arm, Balanced, Single-Dose, Parallel-Group Study Comparing Pharmacokinetics And Pharmacodynamics Of Intas Denosumab (120 Mg/1.7 mL) of Intas Pharmaceuticals Limited, India with Xgeva® Of Amgen Inc., USA And Xgeva Of Amgen Europe B.V., The Netherlands in Normal, Healthy, Adult Human Male Subjects" conducted as per Protocol No. 0568-19. After detailed deliberation, the committee noted the results of the Phase I clinical trial presented by the firm.
New Drugs Division			
5.	ND/MA/24/000119	M/s Precise Biopharma Pvt.	The firm presented the proposal for grant of permission to manufacture and market

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Abaloparatide Injection 3120mcg/1.56ml	Ltd.	of Abaloparatide Injection 3120mcg/1.56ml along with Phase III Clinical Trial Protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial of Abaloparatide Injection 3120mcg/1.56ml, with condition that firm shall provide post-trial access of study drug to subjects for period of one year after completion of clinical trial
SND Division			
6.	SND/MA/22/000273 Paracetamol 1000 mg/4 ml intravenous bolus injection	M/s. Troikaa Pharmaceuticals Ltd.,	In light of earlier SEC recommendation dated 16.11.2022, firm presented the Phase III CT report before the Committee. After detailed deliberation Committee noted following observations: 1. Injection site pain observed in subjects treated with test product Paracetamol 1000 mg/4 ml injected as intravenous bolus over 2 minutes (fast administration rate) reported to be comparable with injection site pain with reference product paracetamol intravenous infusion 1% w/v (100 ml) infused over 15 minutes (slow administration rate) which is further required to be supported by additional study. 2. Adverse events like facial flushing, transient hypotension, arrhythmias, liver toxicity (toxicity by international normalized ratio) has not been observed and reported in the trial results conduct with Paracetamol Injection which are otherwise common side effects of Paracetamol through I.V. route. Firm need to clarity the same with relevant data and additional study. 3. Applied indications i.e. management of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics and treatment of fever are not supported

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			with presented CT study report, literature, data etc. 4. Firm need to address concerns w.r.t. availability of 20 ml syringe for injecting the proposed formulation and its controlled flow rate administration etc. Accordingly, committee recommended that firm should submit the additional data/ literature/ study protocol etc to address above mentioned observations.
FDC Division			
7.	FDC/MA/25/000052 Polmacoxib 2mg + Thiocolchicoside 8mg Capsules	M/s Precise Biopharma Pvt. Ltd	In the light of earlier SEC recommendation dated 16.04.2025, the firm presented the rationality of the proposed FDC before the committee. After detailed deliberation, the committee opined that the firm did not present any scientific justification/rationale for the proposed FDC as pointed out in previous SEC recommendation. Hence, the committee did not recommend for approval of the proposed FDC.
8.	FDC/MA/25/000076 Polmacoxib 2mg/2mg + Thiocolchicoside 4mg/8mg Capsules	M/s Hetero Labs Limited	The firm did not turn up for presentation.