

Recommendations of the SEC (Analgesic & Rheumatology) made in its 08th/25 meeting held on 17.09.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/126/25 Online Submission (50870) Certolizumab pegol	M/s. LUPIN LIMITED	The firm presented phase III clinical study protocol no. LRP/LUBT019/2024/001 Version No.1.0 dated 12-AUG-2025. After detailed deliberation, the committee opined that firm shall submit phase I study data for further review by committee.
Medical Devices Division			
2.	IMP/MD/2024/141942 PEEK-OPTIMA™ Femoral Component (Freedom Total Knee® System)	M/s. Meril Life Sciences India Private Limited	The applicant presented the Clinical Investigation data generated on Indian population on the said device manufactured by M/s Maxx Orthopaedics, USA. They also presented the interim report of the ongoing clinical study in the Country of Origin i.e. USA and other countries. After detailed deliberation, the committee opined that firm shall submit the final Clinical study data of the ongoing studies on the said device along with the copy of marketing approval obtained from the National Regulatory Authority from the country of origin or any other countries with Stringent regulatory authority, for further deliberation in the matter.
New Drugs Division			
3.	ND/CT/22/000025 Triamcinolone Hexacetonide Injectable Suspension USP 20 mg/ml	M/s. Abbott Healthcare Pvt. Ltd.	In the light of earlier SEC (Analgesic & Rheumatology) recommendations dated 03.04.2024, the firm presented the Phase-IV clinical trial report (TRIA-422-0200 Dated 27 MAY 2025) of the drug Triamcinolone Hexacetonide Injectable Suspension. After detailed deliberation, the committee considered the results of the Phase IV clinical trial study.
4.	ND/CT/25/000072 Polmacoxib Capsules 2 mg,	M/s. Precise Biopharma Pvt. Ltd	In line with the condition of the permission for the manufacturing and marketing of the drug Polmacoxib Capsules 2 mg, the firm presented Phase IV clinical trial protocol (Protocol vide no. CT/2023/42 Version No: 00 dated

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			<p>20.06.2023) for Polmacoxib Capsules 2 mg, before the committee.</p> <p>The firm presented the purpose of the study, inclusion criteria, exclusion criteria, discontinuation criteria, study end points, study sites, sample size calculation, etc. along with the regulatory status of the drug Polmacoxib Capsules 2 mg.</p> <p>After detailed deliberation, the committee recommended to revise the phase IV study Protocol to include the followings:</p> <ol style="list-style-type: none"> 1. Firm should increase the sample size. 2. Study duration shall be increased to six months. 3. Bilateral pedal edema and facial Puffiness shall be included in discontinuation criteria. <p>Further, the committee opined that the revised phase IV CT protocol shall be submitted to CDSCO and Phase IV CT report shall be submitted to CDSCO for further review by the committee.</p>
SND Division			
5.	SND/MA/22/000080 Tofacitinib Extended Release Tablets 11mg	M/s. Optimus Pharma Private Limited	The firm did not turn up for the presentation.
6.	SND/MA/22/000273 Paracetamol Injection 1000 mg / 4 ml 1000.000 mg/4 ml	M/s. Troikaa Pharmaceuticals Ltd.	Under Discussion.
7.	SND/MA/24/000226 Triamcinolone Hexacetonide Injectable Suspension USP 20 mg/ml 40.000 mg/2 ml (Pre-filled syringe)	M/s. Abbott Healthcare Pvt. Ltd	<p>Firm presented their proposal along with the justification of rationale and need of Triamcinolone Hexacetonide Injectable Suspension USP 40 mg/ 2 ml Pre-filled syringe (Single Dose) in already approved indication.</p> <p>After detailed deliberation, Committee recommended that firm should submit the proposed prescribing information (PI) regarding usage of Triamcinolone Hexacetonide Injectable Suspension USP 40 mg/ 2 ml Pre-filled syringe (Single</p>

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			Dose) in specific indications and age groups along with relevant literature/ studies/ data etc.
8.	SND/CT/25/000101 Tofacitinib Extended-Release Tablets 11 mg	M/s. Zydus Lifesciences Limited	<p>Firm presented their proposal for grant of permission to conduct Active Post Marketing Surveillance (PMS) Study vide protocol No. C2B05724 before the committee.</p> <p>After detailed deliberation, the committee recommended to revise the PMS study protocol with following changes.</p> <ol style="list-style-type: none"> 1) Study duration to be increased to 9 months. 2) Number of subjects should be increased to at least 300 patients and subjects should be distributed equally among three approved indications. 3) Validated outcome measures to be increased appropriately to demonstrate safety and efficacy. 4) Screening shall be done for Latent Tuberculosis Infection /HIV/Hepatitis C. 5) Serum Procalcitonin to be estimated. <p>Accordingly, firm should submit the revised PMS study protocol to CDSCO for further review by the committee within 15 days.</p>