Recommendations of the SEC (Analgesic & Rheumatology) made in its 11th/25 meeting held on 11.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/163/25 Online Submission (53098) Dexamethasone sodium phosphate	M/s Syngene International Limited	The firm presented phase III clinical study protocol no. SP-102-05 version 1.0 FINAL dated 22 August 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/135/25 Online Submission (51842) LY3502970	M/s Clinical Trials Eli Lilly and Company India Pvt. Ltd.	The firm presented phase III clinical study protocol no.: J2A-MC-GZPT dated 27-June-2025. After detailed deliberation, the committee didn't recommend for following reasons. 1) The company did not reveal whether the WOMAC physical functional scale it will be using in different languages in different parts of the country is translated and validated to ensure reliability for Indian Languages, as the scale is validated in few languages only. 2) In the exclusion criteria point number 13, company did not specifically mentioned about how it is ruling out Melanocortin 4 Receptor deficiency, cushing syndrome or other syndromic obesity. 3) In the exclusion criteria point 52, regarding the use of glucocorticoid therapy for >14 days or use within 90 days the company has given exception to "topical glucocorticoids "which has to be also in exclusion criteria as it is difficult to assess how much he or she has taken the glucocorticoid and how much it suppresses the hypothalamo-pituitary adrenal axis. 4) For comprehensive evolution the functional scores has to be supplemented with objective evidence in the form of either imaging or biomarkers or body composition assessment or any physical function

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			tests. 5) While obesity treatment is known to be clinically beneficial for knee and hip OA, the data presented by the firm regarding Orforglipron did not substantiate any direct disease-modifying action of the drug in OA. No data of OA specific phase II trials of the drug was presented by the firm. 6) The firm has conducted several clinical trials of the same investigational drug for the treatment of diabetes, obesity or overweight, hypertension, and other conditions; however, it has not provided data on how many subjects with obesity or overweight who also had osteoarthritis benefited. From the study, nor has it provided Phase II study data for this indication. Hence, Quantum of benefit in Obesity or overweight patients with Osteoarthritis receiving Investigational drug has not submitted. 7) The firm has not scientifically justified the molecular mechanism of the investigational drug for the treatment of osteoarthritis, including its sustainable effects and base effects on knee cartilage.
Biological Division			
3.	BIO/CT04/FF/2025/51407 BMS-986454 Solution for subcutaneous injection, 150 mg/mL (300 mg/vial)	M/s Syngene International Limited	The firm presented the proposal for grant of permission to conduct Phase Ib clinical trial entitled "A 2-Part, Phase 1b Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of BMS-986454 in Participants with Rheumatoid Arthritis" vide Study protocol no. IM0551014 version 1.0 dated 29-Jul-2025. The committee noted the results of First-in-human Phase I study conducted by the firm in UK in 187 healthy adult subjects. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase Ib clinical trial as per

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			the protocol presented by the firm.
4.	BIO/CT04/FF/2025/52310 Abatacept 125mg/mL solution for injection in Prefilled syringe	M/s. Dr Reddys Laboratories Limited	The firm presented the proposal for grant of permission to conduct Phase I clinical trial entitled "A single-dose, double-blind, parallel-arm, comparative pharmacokinetic study of DRL_AB, US-licensed Orencia®, and EU-approved Orencia® administered by the subcutaneous route to normal healthy male participants" vide Study protocol no. AB-01-008, version 1.0, dated 02 September 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			
5.	SND/MA/22/000080 Tofacitinib Extended Release Tablets 11 mg	M/s. Optimus Pharma Private Limited	Firm presented their proposal for grant of permission to conduct Active Post Marketing Surveillance (PMS) Study protocol before the committee. After detailed deliberation, the committee recommended to revise the PMS study protocol with following changes. 1) All the known adverse effects shall be listed under primary endpoints. 2) All the participant in the study shall be screened for Tuberculosis infection at beginning of study. If any participant is diagnosed with Tuberculosis, they shall be excluded from the study 3) Any participant who experiences chest related issues during participating in the study shall be screened for Tuberculosis infection. If the participant is diagnosed with Tuberculosis, they shall be excluded from the study and treated with standard care for Tuberculosis. 4) After completion of study, all the participant shall be tested for QuantiFERON-TB Gold Test (QFT-G). If any participant is diagnosed with Tuberculosis, they shall be

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			treated with standard care for Tuberculosis. Accordingly, firm should submit the revised Active Post Marketing Surveillance (PMS) Study protocol to CDSCO within 15 days for further review.
6.	SND/MA/25/000234 Upadacitinib Extended Release Tablets 15 mg	M/s. MSN Laboratories Private Limited	Firm presented their proposal for grant of permission to manufacture & market Upadacitinib Extended Release Tablets 15 mg along with Phase-III clinical trial protocol in applied indication before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial study as per the protocol presented by the firm.
7.	SND/IMP/25/000088 Remifentanil Hydrochloride 1 mg/2 mg for Injection	M/s. Themis Medicare Ltd	Firm presented proposal for grant of permission to Import and marketing of Remifentanil Hydrochloride 1 mg/2 mg for Injection for the additional indication for provision of analgesia in mechanically ventilated intensive care patients of 18 years of age and over with justification for the waiver of Phase-III clinical trial. The committee noted that Remifentanil Hydrochloride 1 mg/2 mg for Injection is approved for the applied indication by European Medicines Agency (EMA), UK MHRA and Health Canada. After detailed deliberation, committee recommended that firm should submit the revised package insert in line with the approved SmPC by EMEA in respect of Posology and method of administration, Contraindications, Special warnings and precautions for use including the following: 1. Maximum duration of continuous infusion shall be mentioned. 2. To specify the suitable safeguards for the cessation of the intravenous infusion of the applied drug to avoid withdrawal syndrome. 3. Safety of the drug with the co administration of other CNS depressants

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			is not known and the Physician shall exercise caution to monitor the risk of adverse effects with the co administration of the applied drug with CNS depressants. 4. Safety of the drug in critically ill patients on high dose of inotropes and vasopressors is not available. Accordingly, firm should submit the revised proposed package insert to CDSCO for further review by the committee.
FDC Division			
8.	FDC/MA/23/000343 Aceclofenac IP 1.5 % w/v + Linseed oil BP 3 % w/v + Methyl Salicylate IP 10 % w/v + Menthol IP 5 % w/v Lotion	M/s Lyka Labs Limited	In light of the earlier SEC recommendation dated 06.02.2024, the firm presented their proposal along with justification for the proposed FDC. After detailed deliberation, the firm did not present any credible scientific evidences of the formulation in lotion dosage form. In view of above, the committee did not recommend for the approval of the proposed FDC.