Recommendations of the SEC (Analgesic, Anesthetics & Orthopedics) made in its 01st/26 meeting held on 07.01.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	BABE/CT05/FF/2025/51000 Etodolac 1000 mg Extended Release Tablets.	M/s. Accutest Research Laboratories (I) Pvt. Ltd.	Firm presented the BA/BE study Protocol No. ARL-25-015 Version No. 02 Protocol Date 19-JUN-2025 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only.
Biological Division			
2.	BIO/CT04/FF/2025/53145 Teriparatide Injection 600 µg /2.5ml	M/s Enzene Biosciences Ltd.	The firm presented the proposal for grant of permission to conduct Phase I clinical trial titled "A randomized, Assessor-blind, balanced, Pivotal, Two period, Two treatment, Two Sequence Single-Dose, 2-Way Crossover Comparative Bioavailability Study of Teriparatide Ascend (ENZ201) 20 µg/80 µL Solution for Injection in pre-filled pen of Enzene Biosciences Ltd., India Versus Reference Product, EU approved FORSTEO® (Teriparatide) 20 µg/80 µL Solution for Injection in pre-filled pen of Eli Lilly Nederland B.V., in healthy adult male and female human subjects under fasting conditions"; vide Protocol No.: CL-022-25, Version: 00 dated 05.11.2025 for export purpose. 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
New Drug Division			
3.	ND/CT/25/000098 Ibuprofen Sodium Dihydrate Film-Coated Tablets 256 mg and 512 mg	M/s Lyrus Life Sciences Pvt Ltd	In line with the condition of manufacturing and marketing permission granted to the firm for drug, Ibuprofen Sodium Dihydrate Film-Coated Tablets 256 mg and 512 mg, the firm presented active PMS study protocol (Protocol No:LYR-IBU-001-

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			25, Protocol Version: 03 dated 27 Jun 2025) with drug, Ibuprofen Sodium Dihydrate Film-Coated Tablets 256 mg and 512 mg before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct active PMS study with drug, Ibuprofen Sodium Dihydrate Film-Coated Tablets 256 mg and 512 mg as per the protocol presented by the firm. The firm should submit Active PMS study report to CDSCO for further review by the committee.
SND Division			
4.	SND/MA/22/000165 E-office: SND-11011/82/2025-eoffice Tofacitinib (ER) Tablets 11 mg	M/s. Alkem Laboratories Ltd.	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 for grant of permission to conduct of PMS study as per protocol presented by the firm with the condition to include known adverse effects in the Case Report Form (CRF).
5.	SND/MA/25/000250 Loxoprofen Sodium Powder for Oral Solution 60 mg	Dr. Reddy's Laboratories Ltd.	The firm presented the proposal for grant of permission for manufacture and market of Loxoprofen Sodium Powder for Oral Solution 60 mg for the symptomatic treatment of pain and inflammation in patients with osteoarthritis along with BE report and justification for CT waiver. The firm informed that, in 2008 Loxoprofen Sodium tablets 60 mg were approved in India for applied indication. Loxonin Granules 10% was approved in Japan in 2001. After detailed deliberation, the committee recommended to accept the BE study report and recommended to grant of manufacture and market of Loxoprofen

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			Sodium Powder for Oral Solution 60 mg for applied indication with the following conditions- 1. The package insert/label should include the statement of "Not for children and pediatric patients" and Sodium content in the formulation. 2. The firm should conduct PMS study. Accordingly, the firm should submit PMS study protocol to CDSCO within 03 months from date of approval of the drug product for review by the committee.
6.	SND/MA/23/000272 Etoricoxib Infusion 1.2 mg/ml	M/s. Themis Medicare Ltd.	In the light of earlier SEC recommendation dated 06.08.2024, the firm presented the proposal for grant of permission for manufacture and marketing of Etoricoxib infusion 1.2 mg/ml for additional indication "Short term use in acute painful condition in hospitalized patient of in Emergency/casualty department" before the committee. The firm stated to conduct Subacute toxicity study, Human Pharmacokinetic study (IV vs. IM), Phase III Clinical trial study and to submit fresh CT application along with animal toxicity data & development plan. After detailed deliberation, the committee opined that, firm should submit the Pharmacokinetic Study protocol along with animal toxicity data and development plan for further review.