Recommendations of the SEC (Analgesics, Anaesthetics & Orthopaedics) made in its 02nd/26 meeting held on 10.02.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	MFG/MD/2025/151930 Bone Void filler (Serioss®)	M/s. Serigen Mediproducts Private Limited	The firm presented their proposal for obtaining permission to manufacture their medical device i.e, Bone Void Filler (Serioss®) which does not have predicate device, before the committee. The firm presented the results of the Clinical investigations carried out in the Indian population. After detailed deliberation, the committee opined that the Clinical study data produced is inadequate to demonstrate the safety and efficacy of the device, therefore the firm shall submit the following for further deliberation: 1. Detailed causality assessment report and comments from the concerned Institutional Ethics Committee (IEC) on the reported death case happened during the study. 2. Clinical data shall include patient comorbidities for all enrolled subjects. 3. Clearly specify the maximum width (mm) and length (mm) of bone defects for which the device is intended. Indications must distinctly mention applicability for bone types. 4. Further, the firm shall provide detailed information on the statistical methodology used for the primary endpoint, not all endpoints, in the study including: i. The sample size calculation and assumptions (effect size, power, alpha level). ii. The method used to determine statistical significance. iii. As it is a non-inferiority design, the predefined non-inferiority margin and its clinical justification.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
2.	ND/MA/24/000014 Upadacitinib Extended Release Tablets 15 mg	M/s. Optimus Pharma Private Limited	Firm did not attend the meeting.
SND Division			
3.	SND/MA/23/000303 Flurbiprofen Lozenges 8.75mg	M/s. Unique Pharmaceuticals Laboratories.	In light of the earlier SEC recommendation dated 26.08.2025, firm has presented the bioequivalence study report and Local availability study report of Flurbiprofen Lozenges 8.75mg before the committee. After detailed deliberation, the committee accepted the BE study report & Local availability study report of Flurbiprofen Lozenges 8.75mg and recommended for grant of permission for manufacture and marketing of Flurbiprofen Lozenges 8.75 mg for the indication: Flurbiprofen Lozenges 8.75 mg are indicated in adults and adolescents over 12 years of age for the symptomatic relief of sore throats
4.	SND/CT/25/000148 Tofacitinib Film Coated Extended Release Tablets 11mg	M/s. Hetero Labs Limited	The firm presented the proposal to conduct Active Post-Marketing Surveillance (PMS) Study of Tofacitinib Film Coated Extended Release Tablets 11mg vide Protocol ID. HCR/PMS/TOFRHA/01/2025 version no.1.0 dated 22.01.2025 before the committee. After detailed deliberation, the committee recommended for approval to conduct the Active Post-Marketing Surveillance (PMS) Study as per protocol presented by the firm.
5.	SND/IMP/25/000088 Remifentanil Hydrochloride 1 mg/2 mg for Injection	M/s.Themis Medicare Ltd	In the light of earlier SEC recommendation dated 11.12.2025, the firm has presented the revised package insert before the committee. After detailed deliberation, the committee recommended for grant of permission for import and marketing of Remifentanil Hydrochloride 1 mg/2 mg for Injection for the applied indication for provision of analgesia in mechanically ventilated intensive care patients of 18 years of age and over subject to condition that the firm should conduct Phase-IV clinical trial.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of the drug product for review by the committee.