Recommendations of the SEC (Analgesics, Anesthetics & Orthopedics) made in its 06th/26 meeting held on 11.06.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/75/26 Online Submission (56720) VAY736 (Ianalumab)	M/s. Novartis Healthcare Private Limited.	The firm presented phase III clinical study protocol no.: CVAY736A22301 version no. 00 dated 10-MAR-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/71/26 Online Submission (56794) Nerandomilast	M/s. IQVIA RDS (India) Private Limited.	The firm presented phase III clinical study protocol no.: 1305-0052 VERANDASSc version no. 1.0 dated 21-JAN-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Medical Devices Division			
3.	CI/MD/2025/172879 Seribo Systems CMF Bone Plates & Screws (OsteoForge)	M/s. Osteoforge Medtech Private Limited.	The proposal for the grant of permission to conduct Clinical investigation on the device viz. Seribo Systems CMF Bone Plates & Screws (OsteoForge) was deliberated in the SEC (Analgesics, Anesthetics & Orthopedics) along with expert from Head, Oral and Maxillofacial surgery. After detailed deliberation, the experts recommended for grant of permission to conduct the proposed study with the following amendments: 1. The inclusion criteria should include the subjects of age 6 years to 65 years. 2. The radiographic analysis of the patients should also be carried out after 6 months.
4.	MFG/MD/2025/151930 Bone Void filler (Serioss® and Serioss® Putty)	M/s. Serigen Mediproducts Private Limited.	The proposal for grant of permission to manufacture investigational medical device viz. Bone Void Filler (Serioss and Serioss Putty), was redeliberated before the Subject Expert Committee. The firm has produced the clinical data generated on Indian population along with the Causality assessment report against the adverse event reported during the study

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			along with the information as asked in the previous SEC meeting. After detailed deliberation, the experts recommended for the permission to manufacture the said medical device for sale or for distribution in the country.
BA/BE Division			
5.	BABE/CT05/FF/2025/52547 Coxanto (oxaprozin) 300 mg capsules.	M/s. Admerus Biosciences Private Limited.	The firm presented the BA/BE study proposal vide protocol No. CS24131, Version: 00 Date: 17 Sep 2025 for export purpose only before the committee. After detailed deliberations, the Committee recommended the following: 1) The firm needs to submit safety, toxicity, and tolerability data in healthy Indian subjects, including both male and female volunteers for 1200 mg dose of Oxaprozin. 2) Revise the protocol to include only lactating female subjects whose infants are more than six (06) months of age. The Date of Birth (DOB) of the infant should be incorporated in the Informed Consent Form (ICF) and appropriate documentary evidence shall be obtained and maintained to verify the infant's age. 3) As the proposal involves a special study in a vulnerable population, oversight of the entire study shall be provided by a Community Medicine department of a Government Medical College to ensure adequate monitoring, participant protection, and compliance with applicable ethical and regulatory requirements in addition to the ethics committee. Accordingly, the firm shall submit the above-mentioned data and documents to CDSCO for further review by the Committee.
SND Division			
6.	SND/IMP/26/000024 Diclofenac SodiumTransdermal	M/s. CliniExperts Services Private Limited.	Under Discussion.

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	Patch15 mg/70 sq. cm & 30 mg/140 sq. cm		
7.	SND/CT21/FF/2024/42536 Tapentadol Extended Release Tablets 25mg	M/s. MSN Laboratories Private Limited.	The matter is under discussion.