

Recommendations of the SEC (Analgesics, Anesthetics & Orthopedics) made in its 04th/26 meeting held on 08.04.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/CT/22/000010 File No.:SND-11011/8/2026-eoffice Teriparatide Injection, Solution for Injection in a pre-filled pen 600 mcg/2.4 ml (Synthetic Origin)	M/s. Sun Pharma Laboratories Limited	Firm has presented Phase IV clinical trial Report of Teriparatide Injection, Solution for Injection in Pre-filled pen 600 mcg/2.4 ml (Synthetic Origin) before the Committee. After detailed deliberation, the Committee recommended to accept the study report presented by the firm and recommended to include the Summary of Clinical trial w.r.t. Adverse Event, SAE and Safety of the product in prescribing information. Accordingly firm is requested to submit revised Prescribing Information to CDSCO.
FDC Division			
2.	FDC/MA/24/000261 Domperidone Maleate IP Eq. to Domperidone 10mg + Naproxen IP (SR) 750mg film coated bilayered tablet	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of the earlier SEC recommendation dated on 04.12.2024, the firm presented their proposal along with BE study report and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee considered the BE study report. As regard to Phase III clinical trial protocol, the committee opined following modification: 1. Firm should revise dosing/treatment schedule as per Standard therapeutic treatment guidelines and accordingly inclusion and exclusion criteria should be modified. 2. Firm should include the suitable comparator. Accordingly, firm should submit revised Phase III clinical trial protocol to CDSCO for further review by the

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			committee.
3.	FDC/MA/25/000253 Diclofenac Diethylamine IP 1.16%w/w eq. to Diclofenac Sodium 1.0 % w/w + Thiocolchicoside IP 0.125 % w/w + Linseed Oil BP 3.0 % w/w + Methyl Salicylate IP 10 % w/w + Menthol IP 5 % w/w + Benzyl Alcohol IP 1 % w/w gel	M/s. GMH Laboratories	The firm did not attend the meeting.
4.	FDC/24/2026-eoffice Ibuprofen IP 400 mg + Paracetamol IP 325 mg uncoated Tablet	M/s. Sanofi India Limited	The firm presented the proposal for update prescribing information for the FDC changes based on the updated company core data sheet (CCDS) Version 2.1 dated 16 th October 2025. After detailed deliberation, the committee considered and approved the changes under 10.2 overdoses Management in prescribing information.
5.	FDC/25/2026-eoffice Ibuprofen IP 100 mg + Paracetamol IP 162.5 mg per 5 mL suspension	M/s. Sanofi India Limited	The firm presented the proposal for update prescribing information for the FDC changes based on the updated company core data sheet (CCDS) Version 2.1 dated 16 th October 2025. After detailed deliberation, the committee considered and approved the changes under 10.2 overdoses Management in prescribing information.
6.	FDC/MA/26/000022 Paracetamol 1000 mg + Ibuprofen 300 mg (as sodium dihydrate) per 100 ml Injectable Solution for Intravenous Infusion	M/s. Althea Pharma Pvt. Ltd.	The firm presented their proposal along with justification for BE & Phase III CT waiver before the committee. Firm informed that the proposed FDC is already approved in USA, Australia, UK, New Zealand and Canada. After detailed deliberation, the committee noted that the firm did not present data w.r.t. Ethnic variation or

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			data generated in Indian population. Accordingly, the firm should submit the clinical trial protocol to CDSCO for further review by the committee.