

**Recommendations of the SEC (Analgesics, Anaesthetics & Orthopaedics) made in its 03<sup>rd</sup>/26 meeting held on 11.03.2026 at CDSCO HQ New Delhi:**

<b>S. No</b>	<b>File Name &amp; Drug Name, Strength</b>	<b>Firm Name</b>	<b>Recommendations</b>
<b>BA/BE Division</b>			
1.	BABE/CT05/FF/2025/50034  Aceclofenac 100 mg, Paracetamol 500 mg and Thiocolchicoside 4 mg Tablets	M/s Ajanta Pharma Limited	Firm presented the BA/BE study Protocol No.: BIOS/2025/002, Version No.: 01, Date: 15/04/2025 for export purpose only before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only.
<b>Biological Division</b>			
2.	BIO/CT21/BO/2025/51791  Denosumab (drug substance) 70 mg/mL and Denosumab injection 60 mg/mL (r-DNA origin) in single use pre filled syringe (For subcutaneous use only)	M/s Lupin Limited	The firm presented the proposal for grant of permission to manufacture and market Denosumab (drug substance) 70 mg/mL and Denosumab injection 60 mg/mL (r-DNA origin) in single use pre filled syringe (For subcutaneous use only) based upon the results of comparative phase 1 clinical trial conducted in India to evaluate pharmacodynamic, pharmacokinetic and immunogenicity of drug product along with results of comparative phase 3 global clinical trial conducted in India and Japan to evaluate efficacy, safety and immunogenicity of the drug product in postmenopausal women with osteoporosis.  After detailed deliberation, the committee recommended for grant of permission to manufacture and market Denosumab (drug substance) 70 mg/mL and Denosumab injection 60 mg/mL (r-DNA origin) in single use pre filled syringe (For subcutaneous use only) for the treatment of postmenopausal women with

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			<p>osteoporosis at high risk of fracture.</p> <p>Further firm has also presented proposal for approval of following additional indications by the way of extrapolation inline with indications approved for innovator product by USFDA.</p> <ul style="list-style-type: none"> <li>• Treatment to increase bone mass in men with osteoporosis at high risk of fracture.</li> <li>• Treatment to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for non metastatic prostate cancer.</li> <li>• Treatment to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.</li> </ul> <p>After detailed deliberation, the committee also recommended for approval of aforesaid additional indications subject to the condition that firm shall conduct Phase IV study in India.</p> <p>Accordingly, firm shall submit Phase IV Clinical Trial protocol to CDSCO within 03 months of grant of marketing authorization permission.</p>
3.	BIO/CT04/FF/2025/5 3141  Ustekinumab 45mg/0.5 ml Auto-injector	M/s Lambda Therapeutic Research Limited	<p>The firm presented the proposal for grant of permission to conduct Phase I clinical trial titled "A Phase I, randomized, balanced, open-label, two-treatment, parallel-design, single-dose study to evaluate the pharmacokinetics, safety, and tolerability of Ustekinumab (DMB-3115) 45 mg/0.5 mL Auto-injector following a single subcutaneous injection in comparison with Imuldosa®</p>

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			<p>45 mg/0.5 mL Prefilled Syringe in normal, healthy, adult male subjects"; vide Protocol No.: 0392-24, Version 2.0 dated 31.01.2025 for export purpose.</p> <p>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.</p>
<b>New Drug Division</b>			
4.	ND/CT/25/000098 Ibuprofen Sodium Dihydrate Film-Coated Tablets 256 mg and 512 mg	M/s Lyrus Life Sciences Pvt Ltd	<p>The firm presented revised PMS protocol (Protocol Number: LYR-IBU-001-25, Version: Final Version 02 dated 08Jan 2026) before the committee.</p> <p>After detailed deliberation, committee recommended the conduct of PMS study as per the revised protocol presented by the firm.</p> <p>The results of PMS study should be submitted to CDSCO for further review by the committee.</p>
5.	ND/CT/25/000090 Naldebain ER Injection (Dinalbuphine Sebacate Extended Release 75 mg/ml)	M/s GUFIC BIOSCIENCES LIMITED	<p>The firm presented the proposal for grant of permission to conduct the Phase III clinical trial of drug Naldebain ER Injection (Dinalbuphine Sebacate Extended Release 75 mg/ml), along with Phase III clinical trial protocol (Protocol Number: CRS/25/007, Version No: 1.0, dated 20 November 2025) before the committee.</p> <p>After detailed deliberation, committee recommended that the firm should revise the protocol with the following points:</p> <ol style="list-style-type: none"> <li>1. The firm should include screening for significant organ dysfunction, specifying defined</li> </ol>

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			<p>cut-off values for relevant laboratory test, e.g. preoperative serum creatinine, eGFR, LFT, Serum NT pro BNP, ECG etc along with clinical parameters for screening of significant organ dysfunction in the protocol.</p> <ol style="list-style-type: none"> <li>2. AE and SAE during the study must be measured and recorded by using specific standardized dictionary of SAE/AE. Specific AE/SAE to be measured should include - urinary retention, hypertension, respiratory depression, pain at injection site, abscess at injection site, hematoma at injection site.</li> <li>3. The firm should monitor the SAE/AE through IDMC.</li> <li>4. Warning with respect to the precaution and concomitant treatment should be included in the main text of the protocol.</li> </ol> <p>Accordingly, the firm should submit the revised protocol to CDSCO for further review by the committee.</p>
<b>SND Division</b>			
6.	SND/MA/22/000273 Paracetamol Injection 1000 mg/ 4 ml	M/s Troikaa Pharmaceuticals Ltd.	<p>In light of SEC recommendation dated 17.09.2025, firm presented the matter before SEC for further deliberation.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of Paracetamol Injection 1000 mg / 4 ml for post-operative pain management subject to the following conditions:</p>

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			<p>1) The product shall be used in hospitalized patients only.</p> <p>2) To conduct Active post-marketing surveillance (PMS) to further evaluate safety of product by monitoring the incidence of hypotension, injection-site pain and usage in the liver compromised patients etc.</p> <p>3) a. The package insert shall include detailed instructions for use by clinicians in a hospital setting including preparation, reconstitution, and administration of the product.</p> <p>b. After reconstitution, immediately administer the 20 ml solution as slow I.V. Bolus within 02 minutes. If not administered within 02 minutes, the unused solution to be discarded. Accordingly, firm should submit the revised package insert.</p> <p>Further, firm should submit focused Active PMS study protocol to CDSCO within 03 months from date of approval of the drug product for review by the committee</p>