

Recommendations of the SEC (Analgesic & Rheumatology) made in its 10th/25 meeting held on 12.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	MFG/MD/2025/170055 3-D Scaffold Matrix	M/s. EffecMed Private Limited	<p>The firm presented the proposal for the grant of permission to manufacture for the marketing of the Investigational medical device, viz. 3-D Scaffold Matrix (Brand Name: Dentafuse), which is manufactured by M/s EffecMed Private Limited, Mumbai, India. (Indigenously Developed).</p> <p>The firm has presented pilot and pivotal clinical study data generated on the said device.</p> <p>After detailed deliberation, the committee recommended for consideration of said proposal with the Indication in “following clinical dentistry conditions to augment or reconstruct periodontal or bony defects of the oral, maxillofacial region and bone regeneration procedures: 1. Cystic defects 2. Alveolar ridge preservation 3. Periodontal defects 4. Sinus lift 5.Implant stabilization”, subject to the following conditions:</p> <ol style="list-style-type: none"> 1. The applicant shall submit the phase IV clinical Investigation protocol within three months from the date of approval of marketing authorization for the product. 2. The following statement shall be included in the Disclaimer section of the Instructions for Use (IFU): “This device is intended for use to fill bone voids or gaps up to a maximum length of 25 mm.”

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Biological Division			
2.	E-95538 Denosumab Solution for Injection 60 mg/ml	M/s. Intas Pharmaceuticals Ltd.	<p>The firm presented the final Clinical Study Report (CSR) dated 11-June-2025 for the Phase IV clinical study titled “A prospective follow-up study to evaluate the long-term safety of Intas Denosumab 60mg/ml (PFS) in postmenopausal women and men with osteoporosis at high risk of fracture” (Protocol No. 0043-18) conducted by firm.</p> <p>After detailed deliberation, the committee noted the results of Phase IV study presented by the firm with a recommendation to update the warning with respect to chronic kidney disease-mineral bone disorder (CKD-MBD) under section “Special warnings and precautions for use” of prescribing information in-line with US-PI of innovator PROLIA®.</p> <p>Accordingly, firm should submit the revised prescribing information to CDSCO for evaluation.</p>
SND Division			
3.	MF/SND/22/000074 Ibuprofen solution Infusion 400 mg/100 ml (4 mg/ml)	M/s. Akums Drugs & Pharmaceuticals Limited	<p>The firm presented Post Marketing Surveillance study with protocol ID: VRL-CT-24-019 of the Ibuprofen solution for Infusion 400mg/100ml (4mg/ml) in adults for the short-term symptomatic treatment of acute moderate pain, and for the short-term symptomatic treatment of fever, when administration by intravenous route is clinically justified when other routes of administration are not possible”.</p> <p>After detailed deliberation, the committee recommended to include following in the protocol:</p> <ol style="list-style-type: none"> 1. Dosing schedule & duration as per approved Prescribing

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			<p>information will be recorded and followed.</p> <ol style="list-style-type: none"> 2. Specify the cut off value of eGFR in inclusion criteria. eGFR value below 60 shall be excluded. 3. Patients with Liver function test >3 times of upper normal limit shall be excluded. 4. Monitor serum NT-proBNP level to detect cardiovascular diseases. <p>Accordingly, firm should submit revised protocol to CDSCO for approval within 15 days.</p>