

Recommendations of the SEC (Dentistry) meeting held on 23.12.2024 at CDSCO (HQ), New Delhi

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/23/000041 Endomethasone N	M/s. Septodont Healthcare India Pvt. Ltd.	<p>In light of earlier recommendations dated 20-05-2024, the firm has presented the scientific evidences/literature on clinical trial and safety data on safe use of drug Endomethasone N, before the committee.</p> <p>After detailed deliberation, the committee noted that the following-</p> <ol style="list-style-type: none"> 1. The firm did not present the long term safety data on carcinogenic potential of Endomethasone N. 2. One of the scientific article presented by the firm was sponsored by M/s. Septodont Healthcare India Pvt. Ltd. 3. The firm has presented meta-analysis of similar products which is not proof of their own product. 4. Real world data of patient safety has not been presented. 5. Name of the countries where the firm applied, however approval was not granted could not be clarified by the firm. Hence, the firm is requested to submit the same. <p>In view of the same, the committee recommended that the firm should submit the robust scientific evidences on safety data on safe use of drug Endomethasone N and endodontic failures associated with the use of Endomethasone N should be provided for further review by the committee.</p>