

**Recommendations of the SEC (Dermatology & Allergy) made in its 02<sup>nd</sup>/25 meeting held on 11.02.2025 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	BIO/CT18/FF/2021/26201  Tildrakizumab Injection 100 mg/ml	M/s. Sun Pharmaceutical Industries Ltd.	<p>The firm presented the proposal for grant of permission to import and market Tildrakizumab injection 100mg/ml based on the clinical study results of Phase III clinical trial conducted in India to assess the efficacy, safety and immunogenicity of the drug in Indian patients with moderate to severe plaque psoriasis.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market Tildrakizumab injection 100mg/ml for the indication “Indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy” with the condition to conduct Post Marketing Surveillance study. The PMS study protocol should also include safety parameters for cardiac evaluation and for baseline &amp; post treatment screening of Tuberculosis.</p>
<b>SND Division</b>			
2.	SND/CT/24/000084  Esmolol Hydrochloride Topical Gel 14% w/w	M/s. IPCA Laboratories Limited	<p>The firm presented the proposal for grant of permission to conduct Phase-IV clinical trial of Esmolol Hydrochloride Gel 14% w/w along with Phase-IV clinical trial protocol (Protocol No. Ipc/ESMO/PIV-24, Version:01, Dated: 09.04.2024) before the committee.</p> <p>The firm has informed that CDSCO already issued permission vide no. MF/SND/24/000050 dated 24.04.2024 for manufacture and marketing of Esmolol Hydrochloride Gel 14% w/w in the country with condition to conduct Phase-IV clinical trial in the 400 population.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase-IV clinical trial of Esmolol Hydrochloride Gel 14% w/w as per</p>

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			protocol presented by the firm with the condition that clinical trial sites should be geographically distributed including 50% Government sites.