

Recommendations of the SEC (Dermatology & Allergy) made in its 04th/26 meeting held on 09.04.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	E-113567 Tildrakizumab Injection 100 mg/mL	M/s. Sun Pharmaceuticals Industries Limited	<p>The firm presented the proposal to conduct active post marketing surveillance study of Tildrakizumab Injection 100 mg/mL, titled: “A Multi-Centric, Prospective, Single arm, Open Label, Open Label, Post Marketing Surveillance Study to Evaluate Safety and Efficacy of Tildrakizumab in Patients With Moderate-to-Severe Plaque Psoriasis” as per Protocol No. ICR/25/PMS/004, Version 1.0 dated 12 September 2025.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed post-marketing surveillance study as per the protocol presented by the firm, with the condition that the total study duration shall be 52 weeks.</p> <p>Accordingly, the revised protocol shall be submitted to CDSCO.</p>