

Recommendations of the SEC (Dermatology & Allergy) made in its 75th meeting held on 17.11.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT/22/000025 Tildrakizumab	M/s. Sun Pharmaceutical	<p>In light of the earlier SEC meeting dated 15.03.2022 and 18.08.2022, the firm presented the revised protocol for conduct of Phase III clinical trial with Tildrakizumab Injection 100mg/ml vide Protocol No.ICR/22/005, Version No. 1.0, dated 14th September 2022 titled “A single-arm, multi-centric study to evaluate efficacy, safety and immunogenicity of Tildrakizumab in patients with moderate-to-severe plaque psoriasis”.</p> <p>Committee noted that as the drug is globally approved in 44 countries including US, EU, Canada and Japan, the present study design is single arm, non comparative study to evaluate efficacy, safety and immunogenicity of Tildrakizumab in patients with moderate-to-severe plaque psoriasis and as per US prescribing information Tildrakizumab can be administered in patients with latent tuberculosis, only after appropriate anti TB treatment.</p> <p>After detailed deliberation, the committee recommended to conduct the study as per the presented protocol.</p>
SND Division			
2.	SND/MA/20/000377 Minocycline HCL Topical Gel 4 %	M/s. Glenmark Pharmaceuticals	The firm did not turn up for presentation.
3.	SND/MA/22/000274 Dutasteride Topical Solution 0.05 % w/v	M/s. Shilpa Medicare	<p>The firm presented their proposal for manufacture and marketing of the drug Dutasteride Topical Solution 0.05% w/v with results of efficacy, safety, pharmacokinetics and pharmacodynamic of the Phase II clinical trial and justification for request of Phase III clinical trial waiver before the committee. The committee opined that this product is only available in USA as an OTC product.</p> <p>After detailed deliberation, the committee</p>

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			recommended that the firm should perform Phase III clinical study in Indian population to generate more safety and efficacy data of proposed formulation. Accordingly, the firm should submit the Phase III clinical trial protocol to CDSCO for further review by the committee.
GCT Division			
4.	CT/99/22 Online submission (33788) TEV-45779 Vs. Omalizumab	M/s. Lotus Labs	The firm presented the proposed study protocol no. TV-45779-IMB-30086, amendment 03, dated 10-May-2022 before the committee. After detailed deliberation, the committee recommended for the conduct of the trial with the condition that the H1-antihistamines (preferably the second generation H1-antihistamines in the approved dosage regimen) used as standard care should be uniform across all the study centers in the country.