

Recommendations of the SEC (Dermatology & Allergy) made in its 03rd/25_{meeting} held on 20.03.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2024/4 2756 Ustekinumab solution for injection 45 mg & 90 mg	M/s Johnson & Johnson Pvt. Ltd.	<p>In light of earlier recommendations dated 05.09.2024, the firm presented the additional safety data of South Asian subjects with Plaque Psoriasis in adults.</p> <p>The committee noted that the proposed additional indication is approved in USA, UK, Japan, Singapore, Switzerland and other countries. The committee also noted that there is an unmet medical need in the country.</p> <p>After detailed deliberation, the committee recommended for the grant of approval for the proposed additional indication i.e. for improving health related quality of life in adults with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy of Plaque psoriasis in adults with a condition to conduct Phase IV trial in India in the proposed indication.</p> <p>Accordingly, the firm shall submit the Phase IV protocol to CDSCO within 03 months of approval of additional indication.</p>
SND Division			
2.	SND/MA/25/000007 Roflumilast Cream 0.3% w/w	M/s Mankind Pharma Ltd	<p>Firm has presented their proposal for the manufacturing and marketing of Roflumilast Cream 0.3% w/w for the indication treatment of topical treatment of plaque psoriasis, including treatment of psoriasis in the intertriginous areas, in patient 6 years of age and older with justification of BE waiver and phase III clinical trial protocol.</p> <p>After detail deliberation, the committee opined that the firm should revised their protocol to include following points:</p> <ol style="list-style-type: none"> 1. Amount of drugs applied in terms of FTU on the affected area.

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			<ol style="list-style-type: none"> 2. Specific time of application of the drug so that all the volunteers get uniform treatment 3. specific criteria shall be adopted for randomization. 4. Instead of placebo firm should use emollients 5. Specific lab test shall be included to assess the side effect of the proposed drug. 6. Patients with moderate to severe psoriasis who are receiving other drugs treatment shall be excluded from the study. 7. More number of Geographically distributed sites including proportional Government sites shall be included in the study. <p>Accordingly, firm should submit revised Phase-III protocol to CDSCO for further review by the committee.</p>
3.	SND/MA/21/000448 Alcaftadine Nasal spray 0.125%, 0.25% and 0.50%	M/s Alkem Laboratories Limited	Firm did not turn up for the presentation.