

Recommendations of the SEC (Dermatology & Allergy) made in its 12th/25 meeting held on 17.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/22/000057 Fosravuconazole L-lysine ethanolate Capsules 169.1 mg	M/s Dr. Reddy's Laboratories Ltd	<p>In light of earlier SEC recommendation dated 07.02.2024, firm presented Phase III CT report of Fosravuconazole L-lysine ethanolate Capsules 169.1 mg before the committee.</p> <p>After detailed deliberation, the committee considered the Phase III clinical trial result of Fosravuconazole L-lysine ethanolate Capsules 169.1 mg as presented by the firm and recommended for the grant of permission to manufacture and market drug Fosravuconazole L-lysine ethanolate Capsules 169.1 mg for the proposed indication subject to the condition that</p> <ol style="list-style-type: none"> 1. Firm should conduct Post Marketing Surveillance (PMS) study to establish safety of the drug in all the categories of patients for which the use of drug is indicated and to submit PMS protocol for further review by the committee within 3 months of approval. 2. The drug should be sold by retail only under the prescription of Dermatologist only.
2.	ND/MA/25/000081 Tapinarof Cream 1% w/w	M/s. OM SAI Pharma Pack	<p>The firm presented the proposal for grant of permission to manufacture and market of the drug Tapinarof Cream 1% along with Phase III Clinical Trial protocol titled "A Multicentric, Prospective, Parallel Group, Randomized, Active Controlled, Phase III Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Tapinarof Cream 1% w/w in Comparison with Calcipotriol Ointment 0.005% w/w in Adult Patients for the Topical Treatment of Plaque Psoriasis." (Protocol ID: CT/2025/16 Version 00 Dated - 30/APR/2025)" before the committee.</p>

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			After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial of drug Tapinarof Cream 1% as per protocol presented by the firm.
SND Division			
3.	SND/MA/25/000124 Roflumilast Cream 0.3% w/w	M/s Lyka Labs Ltd	In continuation with earlier recommendation of SEC (Dermatology & Allergy) dated 23/09/2025. Firm has presented revised protocol for the Phase III clinical trial of Roflumilast Cream 0.3% w/w for topical treatment of plaque psoriasis before the committee. After detailed deliberation, the committee recommended to conduct the Phase III clinical trial as per Protocol presented.
4.	SND/MA/23/000040 Tofacitinib Film Forming Lotion 2% w/v	M/s Hetero Health Care Limited	In light of earlier SEC recommendation dated 14.06.2025 the firm presented the Phase III study report for grant of manufacturing and marketing permission for Tofacitinib film-forming lotion 2% w/w before the Committee. After detailed deliberation, the Committee recommended for grant of permission to manufacture and market Tofacitinib film forming lotion 2% w/w for Proposed indication subject to the condition to conduct Active PMS study for a minimum duration of 6 to 12 months. Accordingly, the firm should submit Active PMS Protocol to CDSCO within 3 months of drug product approval.
5.	SND/MA/24/000240 Pirfenidone Topical Gel 8%	M/s Pure and Cure Healthcare Pvt. Ltd	The firm didn't turn up for presentation.
6.	SND/CT21/FF/2024/42233 Roflumilast Cream 0.3% w/w	M/s. Pure and Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 08.10.2025 firm presented the revised Phase III CT protocol vide Protocol ID: VRL-CT-25-002 Version No: 2.0 dated 05-Nov-2025 before the committee. After detailed deliberation, the committee recommended for permission to conduct the Phase III clinical study with following changes:

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			<p>1. Study design shall be double blind instead of open label study.</p> <p>2. At least 50% of the Patients shall be followed up for 6 to 8 months after the end of the treatment for the clearance/reduction of lesion.</p> <p>Accordingly, firm should submit the updated Phase III CT protocol to CDSCO.</p>
FDC Division			
7.	FDC/MA/25/000096 Minoxidil IP 5% w/v + Finasteride IP 0.1% w/v + Latanoprost IP 0.03% w/v per mL Topical solution	M/s Pure and Cure Healthcare Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 21.05.2025, the firm presented the proposal along with IVRT, IVPT and dermal toxicity report before the committee.</p> <p>After detailed deliberation, the committee observed that the firm did not present IVPT and IVRT data to support their proposed FDC scientifically.</p> <p>Accordingly, the firm should submit detailed scientific justification of IVPT and IVRT data to CDSCO for further review by the committee before initiation of Phase III CT study.</p>
8.	FDC/MA/25/000237 Adapalene 0.15 % w/w + Benzoyl Peroxide IP 3.1% w/w + Clindamycin Phosphate IP 1.2 % w/w Topical Gel	M/s Om Sai Pharma Pack	<p>The firm presented the proposal along with Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended to conduct Phase III clinical trial study with the condition that:</p> <ol style="list-style-type: none"> 1. Firm should exclude severe acne vulgaris patients (Grade 3). 2. Firm should incorporate SOP for peer review of photographs. <p>Accordingly, the revised Phase III clinical trial protocol should be submitted to CDSCO for review.</p> <p>Further, after approval from CDSCO the firm should submit Phase III clinical trial report for further review by the committee.</p>