Recommendations of the SEC (Dermatology & Allergy) made in its 05th/26 meeting held on 12.05.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	E-receipt No. 137580 Secukinumab 150 mg/mL Powder (Lyophilized) for solution for injection in vial, Secukinumab 150 mg/mL solution for injection in pre-filled syringe, Secukinumab 150 mg/mL Solution for injection in pre-filled pen	M/s. Novartis Healthcare Pvt. Ltd.	The firm presented the proposal to conduct PMS study titled as "A Prospective, Multicentre, Observational study to assess the Safety of subcutaneous Secukinumab 300 mg solution for the treatment of active moderate-to-severe Hidadrenitis Suppuritiva in adult patients with an inadequate response to conventional systemic HS therapy over a period of 16 weeks" vide protocol no. CAIN457MIN01 dated 20 Feb 2026. After the detailed deliberation, the committee recommended for grant of permission to conduct of the PMS study subject to the following condition: - 1. Considering an anticipated 10% dropout rate, the sample size should be increased to 51–52 subjects to ensure enough evaluable participants. 2. Clinical trial site should be geographically distributed across the country. 3. Number of patients shall be proportionate between government and private clinical trial sites. Accordingly, firm shall submit the revised PMS protocol to the CDSCO.
New Drugs Division			
2.	ND/MA/25/000051 Tapinarof Cream 1%	M/s. Dr. Reddy's Laboratories Ltd.	In light of earlier SEC recommendation dated 23.07.2025, the firm presented Phase III Clinical trial report for manufacturing and marketing permission of new drug, Tapinarof Cream 1% before the committee. The committee also reviewed the prescribing information for proposed drug product. After detailed deliberation, the committee recommended for the grant of permission

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			for manufacturing and marketing of drug, Tapinarof Cream 1% for the proposed indication subject to the conditions that: 1. The committee recommended that the adverse events need further monitoring and the firm should conduct PMS study and submit PMS protocol for further review by the committee within 3 months of approval. 2. The drug should be sold by retail on the prescription of Dermatologist only.
SND Division			
3.	SND/MA/23/000231 Minoxidil tablets 2.5mg	M/s. Akums Drugs & Pharmaceuticals Limited.	In continuation of earlier SEC recommendation dated 07.08.2024, 21.05.2025, the firm presented the revised Phase III Clinical trial protocol before the committee. After deliberation, the committee recommended the following before considering the proposal to conduct the Phase III Clinical trial:- i. Firm shall submit the data of dose-finding study in proposed indication. ii. Firm shall submit safety data in respective population
4.	SND/MA/25/000036 SND/CT21/FF/2025/47827 Bilastine Nasal Spray 0.36%w/v	M/s. Biodeal Pharmaceuticals Limited.	Proposal was deferred for deliberation before Pulmonary SEC committee.
5.	SND/MA/26/000015 SND/CT21/FF/2026/54237 Minoxidil tablet 1 mg	M/s. Cipla Limited.	The firm presented their proposal for grant of permission for the manufacture and marketing of Minoxidil Tablets 1 mg for the treatment of Female Pattern Hair Loss, along with the Phase III clinical trial protocol. After deliberation, the committee recommended that the firm shall submit the following data before considering the proposal to conduct Phase III clinical study.

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			I. Firm shall submit dose-finding study in the proposed indication. II. Firm shall submit safety data of applied product in respective population.