Recommendations of the SEC (Dermatology & Allergy) made in its 13th/25 meeting held on 23.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/25/000113 Tapinarof Cream 1% w/w	M/s. Pure and Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 08.10.2025, the firm presented the proposal for grant of permission to manufacture and market of the drug Tapinarof Cream 1% along with revised Phase III Clinical Trial protocol (Protocol ID; VRL-CT-25-041, Version 1.1 Dated 13-Nov-2025) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial of drug Tapinarof Cream 1% with the condition that firm should revise the inclusion criteria to ensure that no patient should have >10% body surface area (BSA) involvement. Accordingly, the firm should submit the revised protocol to CDSCO
2.	ND/MA/25/000159 Tapinarof Cream 1% w/w	M/s. Emcure Pharmaceuticals Limited.	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 (Protocol No: CE-25-07 Protocol Version No: 1.0, dated 11-Sep- 2025) before the committee. After detailed deliberation, the committee recommended the following changes in the presented protocol: 1) There should be another objective scoring system of severity included namely SCORAD in the study apart from EASI. 2) A standard-of-care (SOC) comparator arm for atopic dermatitis should be included in the study design. 3) SOC should be defined and should be provided to the patients who discontinue or withdraw from the trial. 4) A pediatrician should be included as part of the study team at each clinical trial site.

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			Accordingly, firm should revise the Phase III CT protocol and submit the revised protocol to CDSCO for further review by the committee.
SND Division			
3.	SND/MA/25/000173 Ruxolitinib cream 1.5% w/w	M/s. Sun Pharmaceutical Industries Limited.	In light of earlier SEC recommendation dated 11.11.2025 firm presented the submitted revised Phase III CT protocol vide Protocol. ICR/25/007 before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase III CT with monitoring of SAEs and post-trial access of the drug in the said trial.
4.	SND/MA/25/000139 Phenytoin base cream 1 % w/w.	M/s. Swati Spentose Private Limited.	The firm presented proposal for grant of permission to manufacture and market Phenytoin base cream 1% w/w for the local treatment of Diabetic Foot Ulcers, along with a request for CT waiver before the Committee. The committee noted that the proposed dose is not approved anywhere and failed to justify the request for CT waiver. After detailed deliberation, the Committee did not accept the request for CT waiver and recommended that the firm should submit preclinical data along with proof-of-concept study to support the proposed indication.
5.	SND/MA/25/000182 Ruxolitinib Cream 1.5%	M/s. Torrent Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 11-Nov-2025, the firm presented the revised Phase III CT protocol for grant of permission to conduct Phase III clinical trial for Ruxolitinib Cream 1.5% for the treatment of mild to moderate Atopic Dermatitis in 18 year of age or older before the Committee. After detailed deliberation, the Committee recommended grant of permission to conduct Phase III clinical trial subject to the condition that the patients should followed up to one year for efficacy/ relapse. Accordingly, the firm should submit revised protocol to CDSCO.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
6.	SND/MA/25/000218 Cidofovir Topical Gel 1% w/w and 3 % w/w (New dosage form & new indication)	M/s. Emcure Pharmaceuticals Limited.	The firm presented their Proposal for manufacturing and marketing Cidofovir Topical Gel 1% w/w and 3% w/w for the treatment of cutaneous warts along with Dermal toxicity data and Phase III clinical study protocol before the Committee. After detailed deliberation, the Committee recommended revisions to the Phase III clinical study trial protocol as follows: 1. Standard of care (SOC) arm to be incorporated 2. Power of the study should be at least 90%. Accordingly, sample size to be increased 3. Equal no. of Patients shall be enrolled in SOC and treatment arm & may be smaller in Placebo arm. 4. Stratified analysis of trial drug response should be compared against SOC based on type of warts should be collected and presented. 5. Photographic record should be maintained in addition to the GAIS scale for evaluation. 6. All the Patients who fail in Placebo arm should be provided with SOC. 7. Follow-up should be done every three (03) months for a period of six (06) months. Accordingly, the firm should submit revised Clinical trial Protocol to CDSCO for further review by the Committee.