Recommendations of the SEC (Dermatology & Allergy) made in its 07th/26 meeting held on 09.07.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/95/26 Online Submission (57689) LOU064 (Remibrutinib)	M/s. Novartis Healthcare Private Limited	The firm presented phase III clinical study protocol no. CLOU064R12301 version no. 01 dated 07-MAY-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
New Drugs Division			
2.	ND/IMP/25/000113 Remibrutinib Film-Coated Tablet 25 mg	M/s. Novartis Healthcare Private Limited	In light of earlier SEC recommendation dated 11.02.2026, the firm presented Phase IV Clinical trial protocol for import and marketing permission of new drug, Remibrutinib Film-Coated Tablet 25 mg 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 for import and marketing of drug, Remibrutinib film-coated tablet 25 mg for the proposed indication subject to the conditions that: The drug should be sold by retail on the prescription of Dermatologist only. Further, the committee also recommended for grant of permission to conduct Phase IV clinical trial as per the protocol presented by the firm with following conditions: 1. Under inclusion criteria, the duration of non-response of antihistaminic drug should be fixed. 2. The firm should conduct both safety and efficacy assessment at 28 week. Accordingly, the firm should submit revised Phase IV study protocol to CDSCO.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
3.	ND/MA/25/000071 Tapinarof Cream 1% w/w	M/s. Optimus Pharma Private Limited	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 for manufacturing and marketing of drug, Tapinarof Cream 1% for the proposed indication subject to the conditions that: 1. The committee recommended that as the adverse events need further monitoring, therefore 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			
4.	SND/MA/25/000160 Levocetirizine Dihydrochloride Oral Drops 5 mg/mL	M/s. Dr. Reddy's Laboratories Limited	In continuation of the earlier SEC deliberations dated 08.01.2026, the firm presented safety data for paraben preservatives and Levocetirizine Dihydrochloride Oral Syrup in pediatric patients aged 6 months and above. After detailed deliberation, the committee recommended the grant of permission to manufacture and market Levocetirizine Dihydrochloride Oral Drops 5 mg/mL with the following changes: 1. Indicated for use in the children aged 2 years to 6 years of age. 2. The accompanying graduated dropper size must not exceed 0.5 mL. 3. The proposed prescribing information should clearly mention that the product is not recommended for use in infants and children below 2 years of age.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Accordingly, the firm is required to submit the revised data and Prescribing information to CDSCO.