

Recommendations of the SEC (Dermatology & Allergy) made in its 02nd/26 meeting held on 11.02.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/06/26 Online Submission (54225) GIA632	M/s. Novartis Healthcare Private Limited	The firm presented phase IIb clinical study protocol no. Clinical Trial Protocol CGIA632B12201, Version number: 01 (Amended Protocol) dated 14 Nov 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1) Increase the Number of subjects from India. 2) Day care center should not be a part of clinical trial.
Biological Division			
2.	E-92434 Ixekizumab (r-DNA origin) solution for injection 80 mg/mL	M/s Eli Lilly and Company (India) Pvt. Ltd.	The firm presented the final CSR of Phase IV clinical trial titled “A 24-Week, Multicenter, Open-Label, Single-Arm, Phase 4 Study to Evaluate the Safety of Ixekizumab in Patients with Moderate-to-Severe Plaque Psoriasis and/or Active Psoriatic Arthritis in India” conducted as per Protocol no. IIF-IN-RHCZ, Amendment Number RHCZ(a) dated 14.02.2023. After detailed deliberation, the committee noted the results of the Phase IV clinical trial presented by the firm.
New Drug Division			
3.	ND/MA/25/000159 Tapinarof Topical Cream 1%	M/s Emcure Pharmaceuticals Limited	In light of earlier SEC recommendation dated 23.12.2025, the firm presented revised Phase-III CT protocol (Protocol No: CE-25-07 Protocol Version No: 2.0, dated 06-Jan-2026) of Tapinarof Topical Cream 1% before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial as per protocol presented by the firm.
4.	ND/IMP/25/000113 Remibrutinib Film-Coated Tablet 25 mg	M/s Novartis Healthcare Private Limited	The firm presented the proposal for grant of permission to import and market the drug Remibrutinib Film-Coated Tablets 25 mg along with justification for Phase III

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			<p>Clinical Trial waiver before the committee.</p> <p>After detailed deliberation, the committee noted that there is unmet medical need in a small proportion of patients with difficult to treat urticaria.</p> <p>The committee reviewed the data of global clinical trials on Indian patients and noted that the incidence of bleeding needs further studies in Indian patients.</p> <p>The committee recommended that firm should submit Phase IV CT protocol with adequate sample size which allows meaningful analysis of bleeding adverse effects for review by the committee before grant of market authorization of the drug.</p>
SND Division			
5.	SND/MA/23/000214 Tofacitinib Lotion 2% w/v	M/s Lyka Labs Ltd	The firm has withdrawn the application.
6.	SND/MA/22/000291 Tofacitinib 2% Ointment	M/s. Pure & Cure	The firm did not attend the meeting.
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 17.12.2025, the firm presented the proposal along with scientific justification of IVPT and IVRT data before the committee.</p> <p>After detailed deliberation, the committee considered the justification of IVPT and IVRT data and recommended for grant of permission to conduct the Phase III CT study.</p> <p>Accordingly, the firm should submit the Phase III CT report to CDSCO for further review by the committee.</p>