Recommendations of the SEC (Dermatology & Allergy) made in its 07th/25 meeting held on 23.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/147/24 Online Submission (40047) AC-203 Diacerein 1% Ointment	M/s Veeda Clinical Research Limited	The firm presented protocol amendment version 4.0 dated 23 December 2024 protocol no. AC-203-EBS-007. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
2.	E-61533 Ixekizumab Solution for injection 80 mg/ml	M/s. Eli Lilly & Company (India) Pvt Ltd	The firm presented the proposal for update in Package Insert (Version 2 dated November 2024) for the changes in the Sections of Special Warnings and Precautions for use, Undesirable effects, Post Marketing experience and Patient Counselling Information of the drug product Ixekizumab Solution for injection 80 mg/mL in Pre-filled Autoinjector and Prefilled syringe in line with USFDA PI update approval dated 20.08.2024. After detailed deliberation, the committee recommended for approval of updated package insert Version 2 dated November 2024 of the said drug product for the proposed changes
BA/BE Division			
3.	BABE/CT05/FF/2025/ 48925 CGB-501 Topical Gel with 2.0% and 3.0% Tofacitinib	M/s Raptim Research Pvt. Ltd.	The firm presented the BA/BE study protocol for export purpose only vide No. PR/BE/24/364 Version No.: 01 Date 08-APR-2025 before committee. After detailed deliberation, the committee recommended for grant of permission for the conduct of the study for export purpose only.
SND Division			
4.	SND/MA/21/000448 Alcaftadine Nasal Spray 0.125 %, 0.25 % and 0.50 %,	M/s Alkem	The firm did not turn up for the presentation.

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5.	SND/MA/21/000082 Apremilast Topical gel 2% w/w	M/s Aizant Drug Research Solutions Private Limited	In light of earlier SEC Recommendation dated 11.11.2024, firm presented proposed Prescribing information before the Committee. After detailed deliberation, the Committee recommend to included following in Prescribing Information/ label: 1. Patients should be under supervision of Dermatologist for duration of use of medicine. 2. Patients should periodically visit the Dermatologist at least once in month for duration of use, maximum use upto 3 months. 3. Efficacy and Safety of the drug has been evaluated for usage upto 12 weeks. Further Committee recommended that firm should conduct PMS study for long term safety and efficacy of the drug for which protocol to be submitted within one month of approval**.**
6.	12-160/2017-DC (Pt-Glenmark-snd) Apremilast 10/20/30 mg tablets	M/s. Glenmark Pharmaceuticals Limited	In light of earlier SEC recommendation dated 14.03.2024, the firm presented summary of Phase-IV clinical trial study report with 169 patients data along with justification for closure of the study, real world clinical data and PSUR data before the committee. After detailed deliberation, the committee recommended to accept the Phase-IV clinical trial study report with 169 patients data subject to condition that further periodic safety update reports (PSUR) data for two more years to be submitted by the firm for active psoriatic arthritis.
7.	SND-11011/46/2025-eoffice	M/s Intas Pharmaceuticals Ltd.,	The firm presented report of active PMS study of Tofacitinib Ointment 2% w/w in adult patients with mild to moderate

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	Tofacitinib ointment 2% w/w		atopic dermatitis having flare-up of disease before the committee. After detailed deliberation, the committee recommended to accept the results of active PMS study presented by the firm.
New Drugs Division			
8.	ND/MA/25/000051 Tapinarof Cream 1%	M/s Dr. Reddy's Laboratories 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 titled " A randomized, multi-center, double-blind, parallel group, three-arm, placebo-controlled trial to evaluate the clinical equivalence of Tapianrof cream 1% of Dr Reddy's laboratories Ltd versus VTAMA ® (Tapinarof cream 1%, Dermavent Sciences Inc.) using the clinical endpoint in patients with plaque psoriasis (DRL-IND-NDA30-TAP/2024, version 3.0 dated 17.04.2025)" before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial of drug Tapinarof Cream 1% as per protocol presented by the firm.
9.	ND/MA/25/000071 Tapinarof Cream 1% w/w	M/s Optimus Pharma Private 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 titled " A Phase III, multicentric, comparative, randomized, double-blind, placebo controlled, parallel group clinical study to evaluate the efficacy and safety of Tapianrof Cream 1% in comparison with Placebo of Tapinarof Cream 1% in Adult patients with plaque psoriasis (ICS/OPT/2025-002 Version no. 1.0, Date : 28 MAR 2025)" before the committee. After detailed deliberation, the committee

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			recommended for grant of permission to conduct Phase III clinical trial of drug Tapinarof Cream 1% as per protocol presented by the firm.
10.	ND/IMP/25/000012 Upadacitinib prolonged-release tablets 15 mg	M/s AbbVie Healthcare India Private Limited	The firm presented the proposal for grant of permission to import and market of the drug Upadacitinib prolonged-release tablets 15 mg along with justification for local Phase III Clinical Trial waiver before the committee. After detailed deliberation, the committee did not recommend the waiver of Phase III clinical trial, as there are enough patients of atopic dermatitis in India. Accordingly, the firm should submit the Phase III clinical trial protocol before the committee for further consideration.