Recommendations of the SEC (Dermatology & Allergy) made in its 06th/26 meeting held on 11.06.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/38/26 Online Submission (55543) CGB-501, 3.0% Tofacitinib	M/s. Raptim Research Pvt. Ltd.	The firm presented phase II clinical study protocol no.: CGB-501-02 version no. 1.0 dated 18-FEB-2026. After detailed deliberation, the committee opined that the firm shall submit revised protocol with following for further review by the committee; a) Statistical analysis of sample size shall be submitted with consideration to achieve minimum 30 subjects in the active arm. b) Design of the study shall be three arms study and one arm shall be of 2.0% Tofacitinib gel included for comparing the efficacy of 3.0% Tofacitinib gel and vehicle. c) Detailed Safety monitoring plan including laboratory measures shall be included d) The subjects with Baseline SALT score >50 and <80 shall be removed from the inclusion criteria of the study. e) Inclusion of patients reported outcome measures.
Medical Devices Division			
2.	IMP/MD/2025/172896 Spincare Portable Wound Care System	M/s. Vasu Organics Private Limited	The proposal for grant of permission to import Spincare Portable Wound Care System, for marketing in the country was redeliberated before the Subject Expert Committee. The firm has presented the safety & performance data along with the PMS data of the device marketed in other countries including tropical country After detailed deliberation, the experts recommended for grant of permission to import the investigational medical device

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Biological Division			
3.	BIO/CT04/FF/2026/55176 ASP100 (Dupilumab) Injection 300 mg/2 ml	M/s. Kemwell Biopharma Private Limited	The firm presented the proposal to conduct "A randomized, double-blind, single dose, parallel group, three-arm comparative study assessing pharmacokinetics, safety, tolerability, and immunogenicity of ASP100 injection versus US-licensed Dupixent and EU-approved Dupixent in healthy adult human participants", Protocol no and version: CRD-070 version 1.0 dated 22 August 2025. After detailed deliberation, the committee recommended for grant of permission to conduct comparative pharmacokinetic clinical study between ASP100 (Dupilumab) Injection 300 mg/2 mL manufactured by M/s Kemwell Biopharma Pvt. Ltd., against US-licensed Dupixent and EU-approved Dupixent in healthy adult human participants as per the protocol presented by the firm.
New Drugs Division			
4.	ND/CT/23/000055 Trifarotene 50 µg/g cream	M/s. Galderma India Private Limited	In the light of earlier SEC recommendation dated 09.11.2023, the firm presented Phase IV clinical trial report of drug Trifarotene 50 µg/g cream and justification for waiver of active controlled comparative study before the committee. After detailed deliberation, the committee considered the results of the Phase IV Clinical trial. Further, the committee did not recommend for the waiver of comparative study as there was mismatch between the study subjects evaluated and approved indication for the marketed product. Accordingly, firm should submit detailed clinical data of study subjects (patients with facial and/or truncal acne) to CDSCO for further review by the committee.
SND Division			
5.	SND/CT04/FF/2025/51411 SND/CT/25/000113	M/s. La Pristine Bioceuticals Pvt. Ltd.	The firm presented their proposal for grant of permission to conduct Phase III Clinical Trial for Topiramate Cream 5% w/w indicated for mild to moderate post-acne facial scarring patients before the

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	Topiramate Cream 5% w/w		committee. The committee noted that the firm has not presented the pre-clinical data, dermal toxicity data, proof of concept, dose finding study data etc. Accordingly, the firm needs to submit the said data/ information to CDSCO for further review by the experts.