Recommendations of the SEC (Dermatology & Allergy) made in its 06th/25 meeting held on 11.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/153/24 Online Submission (39193) SAR445229 / amlitelimab	M/s Sanofi Healthcare India Private Limited	The firm presented protocol amendment 06 version 2 dated 07 Feb 2025 protocol no. LTS17367. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with condition that psychiatric helpline no.(24X7) from psychiatric department of concern study site should be provided to the patients.
2.	CT/101/24 Online Submission (39482) Barzolvolimab (CDX-0159)	M/s. PPD Pharmaceutical Development (India) Pvt. Ltd.	The firm presented protocol amendment version 3.1 dated 08 Jan 2025 protocol no. CDX0159-13. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Medical Devices Division			
3.	IMP/MD/2023/111288 Sodium Hyaluronate gel 20 mg/ml + Lidocaine Hydrochloride 3 mg/ml with Calcium Hydroxyapatite microspheres (55.7%) (HArmonyCa® with Lidocaine)	M/s. AbbVie Healthcare India Private Limited	The firm has presented their proposal for the grant of permission to import said device for marketing in the country along with Clinical data generated on the device globally. After detailed deliberation, the expert committee recommended for consideration of the said proposal for proposed indication, subject to the condition that the said device should be used by a qualified Post-graduate dermatologist or plastic surgeons who has undergone proper training for carrying out the procedure. The IFU shall include the same for marketing in the country.
BA/BE Division			
4.	BABE/CT05/FF/2024/ 44109 Ketoconazole 2% Cream	M/s. Cliantha Research Limited	In continuation to earlier SEC (Dermatology & Allergy) meeting dated 22.04.2025, the firm presented details of studies published for other drug products with dOFM technology. After detailed deliberation the committee did not recommend for grant of

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			permission to conduct the proposed BE study due to following- 1) There is no approval of dOFM technology by any regulatory agency for BE purpose. 2) Published safety data with dOMF technology for ketoconazole 2% cream for bioequivalence evaluation in healthy subjects is not available. 3) There is no specific regulatory communication from the country of submission regarding usage of dOFM technology in conduct of BE study with ketoconazole 2% cream. 4) The dOFM technique is more invasive and non-beneficial on healthy subjects.
SND Division			
5.	SND/MA/21/000448 Alcaftadine Nasal Spray 0.125 %, 0.25 % and 0.50 %,	M/s Alkem	Firm did not turn up for the presentation.
6.	SND/MA/25/000045 Pentosan Polysulfate sodium 0.1% w/w and 0.5 w/w cream	M/s. Swathi Spentose PVT.LTD	In light of earlier SEC recommendation dated 21.05.2025, the firm presented the proposal for grant of permission to manufacture and market of Pentosan polysulfate sodium cream 0.1 % w/w and 0.5 % w/w proposed for Symptomatic local treatment of superficial venous disorders such as heaviness and tightness in the legs with varicose veins in adults and superficial hematomas caused by blows, in adults before the committee along with other invited experts i.e. Surgeons, General Physician and Haematologist. After detailed deliberation, the committee recommended to submit and present more clinical and literature data on Global and Indian population in support of the proposed indications for Pentosan polysulfate sodium cream 0.1 % w/w and 0.5 % w/w.
7.	SND/IMP/24/000080 Abrocitinib tablets 50 mg, 100 mg & 200 mg	M/s. Pfizer Products India Private Limited	The firm presented proposal before committee for grant of waiver to condition no. (X) to allow conduct of Active surveillance study in lieu of Phase IV CT study for Abrocitinib Tablets 50 mg, 100 mg, 200 mg for the treatment of

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			moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy. Firm informed that the proposal for waiver of Phase IV CT study for adults population was deliberated before SEC committee on 05.09.2024 and committee opined to conduct the active surveillance study in adults population. Firm also presented the overview of 7 Global Phase 3 studies conducted as part of Abrocitinib clinical development program along with Real World Evidences overview. The committee noted that Phase III CT study (Study No. B7451094) was conducted in India on 200 patients which included 33 (Thirty-three) adolescent patients. After detailed deliberation, the committee recommended that firm should conduct Phase IV CT study in adolescents population as: a) The number of Indian adolescent subjects in Phase III CT study was 33 (thirty-three) only. b) The data presented lacks long term safety findings in Indian adolescents population.
New Drugs Division			
8.	ND/CT/21/000101 Abrocitinib 100 mg and 200 mg tablet	M/s Pfizer Products India Private Limited	In light of earlier SEC recommendation dated 15.02.2022, firm presented Phase III CT report of Abrocitinib 100 mg and 200 mg Tablets before the committee. After detailed deliberation, the committee considered the Phase III clinical trial result of Abrocitinib 100 mg and 200 mg Tablets as presented by the firm
FDC Division			
9.	FDC/CT/25/000001 Clindamycin Phosphate IP 1.2%	M/s Precise Biopharma Pvt. Ltd.	As per the condition mentioned in Form CT-23 dated 11.01.2024, the firm presented Phase IV CT protocol before the committee.

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	w/w eq. to Clindamycin 1%w/w + Hydrous Benzoyl Peroxide IP eq. to anhydrous Benzoyl Peroxide 3.75% Topical Gel		After detailed deliberation, the committee recommended for conducting the Phase IV CT study. The result of the study should be submitted to CDSCO for review by the committee