Recommendations of the SEC (Dermatology & Allergy) made in its 12th meeting held on 05.12.2024 & 06.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/141/243 Online Submission (33342) SAR445229/ Amlitelimab	M/s Sanofi	In light of earlier SEC Recommendation dated 08.10.2024, now the firm presented protocol amendment 01 version 01 dated 20.11.2023 protocol no. EFC17559. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/141/23 Online Submission (35240) SAR445229/ Amlitelimab	M/s Sanofi	The firm presented Increase the number of subjects in the study from 25 to 40 protocol no. EFC17559. After detailed deliberation, the committee recommended for approval of Increase the number of subjects in the study from 25 to 40 as presented by the firm
3.	CT/27/23 Online Submission (36058) Amlitelimab	M/s Sanofi	The firm presented waiver of CT NOC condition that the adolescent subjects shall not be included in the study for protocol amendment 02 version 01 dated 29 November 2023 protocol no. LTS17789. After detailed deliberation, the committee recommended for waiver of CT NOC condition that the adolescent subjects shall not be included in the study for protocol amendment 02 version 01 dated 29 November 2023 as presented by the firm.
4.	CT/137/24 Online Submission (46462) Finasteride + Minoxidil	M/s Ethicare	The firm presented phase 3 clinical study protocol no. ECTS/24/008 version 00 dated 06 November 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
5.	CT/138/24 Online Submission (46511) Clindamycin +Tretinoin	M/s Ethicare	The firm presented phase 3 clinical study protocol no CLITRET/VER version 3.0 dated 11 July 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
6.	FDC/MA/24/000242 Adapalene 0.15 %w/w +Benzoyl Peroxide 3.1 % w/w +Clindamycin Phosphate 1.2%w/w	Glenmark Pharmaceuticals Limited	The firm presented their proposal along with justification for BE& phase III CT waiver before the committee. After detailed deliberation, the committee did not considered the justification for CT waiver and recommended to conduct Phase-III CT study with proposed FDC. Accordingly, the firm should submit Phase III CT Protocol for further review by the committee.
New Drug Division			
7.	ND/CT/24/000050 Clascoterone Cream 1% w/w	M/s Om Sai Pharma Pack	In light with earlier SEC recommendations dated 05.09.2024, the firm presented revised Phase-III CT protocol of drug Clascoterone Cream 1% w/w. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial as per the protocol presented by the firm.
SND Division			
8.	SND/IMP/24/000080 Abrocitinib Tablets 50mg, 100mg, 200mg (Additional indication)	M/s Pfizer Products India Private Limited	The firm presented its application for grant of permission to import Abrocitinib tablets 50mg, 100mg and 200mg for sale or for distribution along with Phase III clinical study data to the committee. The committee noted that the proposed additional indication of Abrocitinib tablets 50mg, 100mg and 200mg is approved in USA, Europe and other countries. After detailed deliberation, the committee recommended for grant of import permission for sale or for distribution of Abrocitinib tablets 50mg, 100mg and 200mg indicated for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy with subject to condition that the firm should conduct Phase-IV clinical trial study.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of the drug product for review by the committee.