Recommendations of the SEC (Dermatology & Allergy) made in its 05th/24 meeting held on 14.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/46/24 Online Submission (42650) Amlitelimab	M/s. Sanofi	The firm presented Phase III clinical study protocol No. EFC17600 version No. 01 dated 01.02.2024. After detailed deliberation, the committee opined that the firm should submit preliminary analysis of primary data of subjects above 18 years in India for further review by the committee.
2.	CT/146/22 Online Submission (32406) Remibrutinib (LOU064)	M/s. Novartis	The firm presented protocol amendment version 01 dated 28.02.2024 protocol No. CLOU064A2303B. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
3.	SND/MA/23/000291 Dutasteride Capsules IP 0.5mg	M/s. Dr. Reddy's Labs Limited	In light of earlier recommendation dated 07.02.2024, the firm has submitted the safety data for Dutasteride for the proposed additional indication – "for the treatment of Male Androgenic Alopecia". The firm presented the safety data in presence of Urologist. During deliberation, the committee noted that the drug Dutasteride has terminal elimination half-life of approximately 5 weeks at steady state and associated with significant incidence of adverse events including sexual impotence. Therefore, committee opined that the firm should conduct Phase III clinical trial and include the IIEF (International Index of Erectile Function) questionnaire. Accordingly, the firm should submit Phase III study protocol to CDSCO for further review by committee.
4.	SND/MA/24/000035 Triamcinolone Acetonide Nasal	M/s. Pontika Aerotech Limited	The firm has presented the proposal for manufacturing and marketing of Triamcinolone Acetonide nasal spray USP 55 mcg along with their justification

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Spray USP 55 mcg		for CT Phase III waiver. The committee noted that the said product is already approved in USA since 1957 and in the year 2013 it has been notified as OTC drug. Further, it is approved in the UK, and Canada also. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Triamcinolone Acetonide nasal spray USP 55 mcg with the condition to conduct Phase IV clinical trial in 400 subjects. Accordingly, the firm should submit Phase IV CT protocol within 3 months of the approval of the drug to CDSCO for further review by the committee.