Recommendations of the SEC (Dermatology & Allergy) made in its 04th/25 meeting held on on 22.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/27/23 Online Submission (38047) Amlitelimab 250 mg/ 2 ml solution	M/s SANOFI HEALTHCARE INDIA PRIVATE LIMITED	The firm presented for Increase in number of adolescent subjects from 07 to 15 in India protocol no. LTS17789. After detailed deliberation, the committee recommended for Increase in number of adolescent subjects from 07 to 15 in India as presented by the firm.
2.	CT/46/24 Online Submission (38206) SAR445229/ Amlitelimab	M/s SANOFI HEALTHCARE INDIA PRIVATE LIMITED	The firm presented protocol amendment 03 version 1 dated 01 October 2024, protocol no. EFC17600 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
BA/BE Division			
3.	BABE/CT05/FF/2024/ 44109 Ketoconazole 2% Cream	M/s. Cliantha Research Limited	The firm presented BA/BE study Protocol No. C1B04382 Version No. 01 Protocol Date 21-JUN-2024 for export purpose only. After detailed deliberation, the committee observed that the proposed Dermal Open Flow Microperfusion (dOFM) technology is not approved by any regulatory agency (for administration of drug). Therefore, the firm needs to submit status of approval of the said technology or clear regulatory recommendation for use of this technique in clinical trials for further review by the SEC committee.
SND Division			
4.	SND/MA/25/000027 Ruxolitinib cream 1.5% w/w	M/S Sun Pharmaceutical Industries Limited,	The firm presented the proposal for manufacturing & marketing of Ruxolitinib cream 1.5% w/w for the topical treatment of non segmental vitiligo in adult and paediatric patients 12 years of age and older along with proposal for conduct of Phase-III clinical study vide protocol No. ICR/24/008 Version 1.0 dated 22/Oct/2024 before the committee. Ruxolitinib is Janus kinase (JAK) inhibitor and Ruxolitinib cream 1.5%

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			w/w is approved for the topical treatment of non segmental vitiligo in adult and paediatric patients 12 years of age in USA on July 2022. The committee noted that the mechanism of action of comparator arm Deca-peptide and proposed Ruxolitinib cream 1.5% w/w are different. Firm need to justify for selection of Deca-peptide as comparator arm. Further, exposure to sunlight/commercial UVB light in Deca-peptide comparator arm for 24 weeks to be standardized.
5.	SND/MA/23/000155 Tofacitinib Ointment 2% w/w	M/s Precise Biopharma Pvt. Ltd	Under discussion.