Recommendations of the SEC (Dermatology & Allergy) made in its 11th/25 meeting held on 11.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/48/25 Online Submission (49317) Abrocitinib (PF-04965842)	M/s Pfizer Limited	In light of earlier SEC recommendation dated 21.05.2025, the firm presented phase III clinical study protocol no. B7451031, Final protocol dated 23 Dec 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the children aged 6 to less than 12 years shall be included in the study.
Medical Devices Division			
2.	IMP/MD/2025/163968 Poly-L-Lactic Acid	M/s.GALDERMA INDIA PRIVATE LIMITED	The firm presented the proposal for the grant of permission to import for marketing of the Investigational medical device, viz. Poly-L-lactic acid (Brand Name: Sculptra), which is manufactured by M/s. Q-Med AB, Sweden (country of origin Italy). The said device is approved for marketing in countries viz. USA, Australia, Canada etc for more than two years. The firm has presented clinical evidence and Post-Marketing Surveillance data generated on the said device. After detailed deliberation, the committee recommended for consideration of said proposal, subject to the following conditions: 1. The proposed product shall be sold and used exclusively by experts who are adequately trained in its application and operation. 2. The applicant shall submit annual data for a period of four years with regards to detailed information on all procedures performed in the Indian population, along with comprehensive follow-up details of the patients treated.
3.	CI/MD/2024/125677 PVR system®	M/s. S.S. HEALTHCARE	The proposal for the grant of permission to conduct Clinical investigation on the device viz. PVR system® was re-deliberated in the SEC (Dermatology &

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			Allergy) along with experts from General Surgery, endocrinologist and diabetologist. After detailed deliberation, the experts recommended for the conduct of the proposed study vide Protocol no. D19_ Clinical Investigation plan V1.4 with date 11/03/2025with the condition that the protocol should include the biopsy procedure to be followed as well as the number of biopsy performed per person per visit, during the study. Also, the protocol shall ensure that during the study, the subjects enrolled should adhere to a fair glycemic control of less than 8% Hba1c.
Biological Division			
4.	E-115798 Ustekinumab injection 45 mg/0.5 mL	M/s. Biocon Biologics Limited	The firm presented the Clinical study report of clinical trial titled "A Phase I, Randomized, Open-Label, 2-Arm, Parallel Design Study in normal healthy subjects to evaluate Pharmacokinetics, Safety and Tolerability of Bmab 1200-Autoinjector (Biosimilar Ustekinumab) after single subcutaneous injection in comparison with Bmab 1200 -Prefilled Syringe (Biosimilar Ustekinumab)". Conducted as per Protocol number BIO-USTEKI-104, Version1.0, dated 17.05.2023. After detailed deliberation, the committee noted the results of the Phase I clinical trial presented by the firm.
SND Division			
5.	SND/CT/25/000111 Minocycline Hydrochloride Topical Gel 4% w/w	M/s. PURE & CURE HEALTHCARE Pvt. Ltd.	The firm presented the proposal to conduct Phase IV study for Minocycline Hydrochloride Topical Gel 4% w/w before the Committee. After detailed deliberation, the Committee opined that Phase IV Clinical trial protocol to be revised for the followings: a. Inclusion criteria should be updated to include pregnancy testing for eligible female subjects; b. Study design should be non-inferiority trial, with the comparator

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			arm receiving standard of care treatment; c. Statistical power of the study should be set at a minimum of 90% to ensure robustness of the findings. Accordingly, the firm should submit revised Phase IV Protocol within fifteen (15) days to CDSCO for further review by the Committee.
6.	SND/MA/25/000173 Ruxolitinib cream 1.5% w/w	M/s. Sun Pharmaceutical Industries Limited	The firm presented the proposal for grant of permission to conduct the Phase III Clinical Trial of Ruxolitinib cream 1.5% w/w for the treatment of patients with mild to moderate atopic dermatitis (AD). After detailed deliberation, the Committee recommended for grant of permission to conduct Phase III clinical trial with following changes: 1. Firm should keep the photographic record while conducting Phase III CT study. 2. Firm should use SCORAD scoring system in addition to EASI scoring system for study 3. Accordingly, firm should submit the revised Phase III CT protocol to CDSCO.
7.	SND/IMP/20/00082 Estradiol 1.53mg/ actuation transdermal spray	M/s. Themis Medicare Limited	The firm did not turn up for the presentation.
8.	SND/MA/25/000182 Ruxolitinib Cream 1.5% w/w	M/s. Torrent Pharmaceuticals Ltd.	The firm presented the proposal for grant of permission for manufacturing and marketing Ruxolitinib cream 1.5% w/w along with Phase-III Clinical trial protocol. After detailed deliberation, the Committee recommended for grant of permission to conduct Phase III clinical trial with following changes. 1. Power of the study should be at least 90%. 2. Treatment period should be kept as 8 weeks. 3. SCORAD scoring system to be used in addition to EASI scoring system for study.

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			4. The protocol shall define/specify the standard of care treatment. Accordingly, firm should submit the revised Phase-III clinical trial protocol to CDSCO