Recommendations of the SEC (Dermatology & Allergy) made in its 05th/25 meeting held on 21.05.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/47/25 Online Submission (49315) Abrocitinib (PF-04965842)	M/s Pfizer Limited	Under discussion
2.	CT/48/25 Online Submission (49317) Abrocitinib (PF-04965842)	M/s Pfizer Limited	The firm presented phase III clinical study protocol no. B7451031 Final Protocol dated 23 Dec 2024. After detailed deliberation, the committee opined that the firm shall submit safety , efficacy and pharmacokinetic data in Children 6 years to 12 years for further review by the committee.
SND Division			
3.	SND/MA/25/000045 Pentosan polysulfate sodium 0.1 % w/w and 0.5 % w/w cream,	M/s Swati Spentose Private Limited	The committee noted that Dermatologists generally don't prescribe this product. Firm also confirmed that the product is generally prescribed by Surgeons and General Physicians. Therefore, the proposal may be deliberated in SEC meeting inviting experts from General Surgery and General Physician.
4.	SND/MA/22/000291 Tofacitinib Ointment 2% w/w	M/s Pure & Cure Healthcare Pvt.Ltd.	The firm presented the proposal for grant of permission to conduct Active Post Marketing Surveillance (PMS) Study vide protocol No. SB-IND-CT-090, Version 1.0 dated 03.02.2025 before the committee. After detailed deliberation, the committee recommended for approval to conduct the study as per the protocol presented by the firm.
5.	SND/MA/22/000194 Tofacitinib Ointment 2% w/w	M/s Mascot Health Series Private Limited	The firm presented the proposal for grant of permission to conduct Active Post Marketing Surveillance (PMS) Study vide protocol No. MCR/CT/0125/01, Version 00 dated 31.01.2025 before the committee. After detailed deliberation, the committee recommended for approval to conduct the

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			study as per the protocol presented by the firm.
6.	SND-16011(11)/239/2024-eoffice Hydroxyzine Hydrochloride Sustained Release Tablet 50mg	M/s Dr. Reddy's Laboratories Ltd.	Under Discussion.
7.	SND/MA/23/000231 Minoxidil tablets 2.5mg	M/s. Akums Drugs & Pharmaceuticals Limited	In light of earlier SEC recommendation dated 07.08.2024, the firm presented the Phase III Clinical trial protocol vide Protocol No. VRL-CT-24-030, Protocol Version 1.0, Dated:11.12.2024 before the committee. After detailed deliberation, the committee opined that 1. Firm shall revise Form CT-21 w.r.t. indication by mentioning Androgenic Alopecia only, in line with the proposed Phase III CT study. 2. 5 mg strength should be removed for the study. 3. Study duration should be increased to one year. 4. Assessor blinding should be done in protocol. 5. Patients not responding (or) not tolerant should be discontinued. Accordingly, firm should submit the revised protocol to CDSCO for further evaluation by the committee in presence of Cardiology expert, since long term usage of the drug may lead to cardiac side effects.
New Drugs Division			
8.	ND/MA/24/000066 Clascoterone Cream 1% w/w	M/s Dr Reddys Laboratories Limited	In light of the earlier SEC recommendations dated 07.08.2024, 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.
FDC Division			

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
9.	FDC/MA/25/000096 Minoxidil IP 5 % w/v + Finasteride IP 0.1 % w/v + Latanoprost IP 0.03 % w/v Topical solution	M/s Pure and Cure Healthcare Pvt. Ltd	The firm presented the proposal along with rationality, justification for BE waiver and Phase III CT protocol before the committee. After detailed deliberation, the committee considered the request for BE waiver with the conditions that the firm should submit following reports: 1. In-vitro Release Test 2. In-vitro Permeation test 3. Animal Dermal Toxicity report As regard to Phase III CT protocol, the committee recommended for conduct of the Phase III clinical trial. Accordingly, the firm should submit the result of above tests to CDSCO for further review by the SEC before initiation of the Phase III clinical trial.