Recommendations of the SEC (Dermatology & Allergy) made in its 77th meeting held on 12.01.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	75/Phase IV/Reliance/17-BD Infliximab	M/s Reliance Life Sciences Pvt. Ltd.	The firm presented the Phase IV clinical trial report conducted as part of permission granted for the additional indication of "plaque psoriasis". After detailed deliberation, the committee noted the results of the Phase IV clinical study as presented by the firm.
2.	BIO/CT/22/000125 Ixekizumab Solution for injection 80mg/ml	M/s Eli Lilly and company	The firm presented the Phase IV clinical study protocol titled "A 24 week multicentre, open-label, single-arm, phase IV study to evaluate the safety of Ixekizumab in Patients with moderate-to-severe plaque psoriasis or active psoriatic arthritis in India" Protocol I1F-IN-RHCZ dated 05.05.2022 as per the condition of import and marketing permission of the drug. After detailed deliberation, the committee recommended for the conduct of the Phase IV study with the following condition: 1. Patients should be evaluated for active tuberculosis by quantiFERON TB Gold test and chest X-ray at 24 week of the treatment. 2. Patients should be evaluated for disease relapse, duration of the disease and response to other drugs before inclusion of the patients in the study. Accordingly, the firm should submit revised protocol to CDSCO for further evaluation.
SND Division			
3.	SND/MA/20/000316 Clobetasol Propionate Shampoo 0.05% w/w	M/s Onknet Healthcare	The firm presented the proposal of manufacture and market of Clobetasol Propionate shampoo 0.05%w/v for the topical treatment of moderate to severe forms of scalp psoriasis in adult alongwith clinical trial justification, some published clinical studies and global approval status of the applied drug product before the committee. After detailed deliberation, the committee recommended that the firm should conduct Phase III Clinical trial against the

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			standard comparator available in Indian market to prove non inferiority/superiority of their product. Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review by the committee.
4.	SND/CT/22/000033 Diperoxochloric acid topical solution 0.29mg/ml	M/s Centaur Pharmaceuticals	In light of earlier recommendation of SEC dated 14-09-2022, firm submitted revised Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial as per the protocol presented. However before grant of permission of clinical trial, comments of plastic surgeon to be obtained.
FDC Division			
5.	FDC/MA/22/000355 Salicylic acid IP+ Luliconazole IP (3%+1%) cream	M/s. Synokem Pharmaceuticals Ltd.	The firm presented its proposal along with Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III Clinical trial with the following conditions: 1. Patients with ear disorders should be excluded from the study. 2. Autoimmune deficiency syndrome term should be elaborated or corrected. 3. Product should not be applied on delicate areas of skin, flexures and near to eyes.
Medical device Division			
6.	IMP/MD/2020/20592 GLUBRAN Tiss 2 Skin adhesive	M/s. Advanced Lifesciences Pvt. Ltd.	The firm presented its proposal for grant of permission to import and market the proposed product in the country before the committee. After detailed deliberation, the committee recommended for grant of permission to import and market the proposed product GLUBRAN Tiss 2 Skin adhesive in the country with the condition that firm should conduct Phase IV post Marketing Clinical Investigation of the proposed product in the country on Indian population. Accordingly, firm shall submit Post Marketing Clinical Investigation Protocol

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			to CDSCO within 3 months from date of permission for further review by the SEC which should include a surgeon.
BA/BE Division			
7.	12-09/2022/BA-BE/Misc-21/DC Roflumilast Cream 0.3%	M/s Cliantha Research Ltd., Ahmedabad	The firm didn't turn up for presentation
Additional Agenda GCT Division			
8.	CT/173/22 Tildrakizumab 100mg/ml	M/s Sun Pharma	The applicant presented Phase II/III clinical trial protocol no. TILD-19-12 amendment No. 2.0 dated 21.11.2022 before the committee. The committee noted that the drug is approved in US and EU countries in adult with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study with condition that the sponsor should submit rescue management plan and provide effective standard of care treatment free of cost to non-responding trial subjects till 52 weeks of study period.
SND Division			
9.	SND/CT/22/000020 Tofacitinib Ointment 2% w/w	M/s Lyka Labs	In light of earlier SEC recommendation dated on 15.12.2022, the firm presented safety assessment data of first 50 patients enrolled in Phase III clinical trial of Tofacitinib Ointment 2% w/w (CT NOC No. CT/SND/010/2022 dated 17.05.2022) before the committee. Committee noted that there is no safety signal in first 50 patients. After detailed deliberation, the committee recommended that the firm should continue the clinical trial as per approved protocol. The firm should report to CDSCO in case of any SAEs related to clinical trial.