Recommendations of the SEC (Dermatology & Allergy) made in its 78th meeting held on 15.02.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2022/ 31744 Spesolimab concentrate for solution for infusion 450 mg/vial	M/s. Boehringer Ingelheim India Private Limited	In continuation to the earlier SEC meeting held on 13.10.2022, the proposal of the firm was re-deliberated as per the firm's request with justification wherein the firm presented for import and marketing of Spesolimab concentrate for solution for infusion 450mg/vial indicated for generalized pustular psoriasis (GPP), with local clinical trial waiver and proposed to conduct global Phase IV study including Indian patients. The committee noted that GPP is a rare disease & is potentially life threatening with a pathway of IL 36 in its pathogenesis. Spesolimab is an IL-36 inhibitor andhas received orphan drug designation and breakthrough therapy designation for treatment of GPP in US. Presently there is no similar drug therapy available in India resulting in an unmet medical need. The drug is currently approved in US, Japan, EU, China and Taiwan. The firm has also proposed to conduct global Phase-IV study including Indian patients which would be open label safety trial to assess the effect of immunogenicity on pharmacokinetics (PK), safety and efficacy on re-treatment of flares that occurs after the first flare incidence has been treated and resolved in GPP flare. After detailed deliberation, the committee recommended for grant of permission to import and market Spesolimab concentrate for solution for infusion 450mg/vial for treatment of flares in adult patients with Generalized Pustular Psoriasis (GPP) subject to the following conditions: 1. Global Phase IV study should include reasonable number of patients from India. 2. There should be screening of patients by QuantiFERON-TB Gold test for tuberculosis and positive patients should be excluded from the study. Accordingly, the firm is requested to submit global Phase IV clinical trial

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			protocol within 3 months of import and marketing permission.
SND Division			
2.	SND/MA/22/000194 Tofacitinib Ointment 2 %	M/s. Mascot Health	The firm presented the Phase III clinical trial protocol before the committee as per manufacturing and marketing permission of Tofacitinib Ointment 2% for the treatment of mild to moderate atopic dermatitis (AD). After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase III clinical trial as per the protocol presented subject to the following conditions: 1) Post trial access of standard of care to the patients should be included in the clinical trial protocol for patient's safety. 2) The firm should present the data of first 50 patients (equally distributed in each arm) enrolled in the study for review by the committee, prior to further recruitment of the patients in the clinical trial. 3) The firm should use EASI and SCORAD scales to monitor patients' disease status. Accordingly, the firm should submit revised clinical trial protocol to CDSCO.
FDC Division			
3.	FDC/MA/23/000016 Halobetasol propionate USP 0.1mg + Tazarotene 0.45mg topical lotion	M/s. Sun Pharmaceuticals	The firm did not turn up for presentation.
4.	FDC/IMP/23/000001 Latanoprost 0.03% w/v + Finasteride 0.1%w/v + Minoxidil 5%w/v topical solution	M/s. Apodictic	The firm did not turn up for presentation.
GCT Division			
5.	CT/160/22 Online Submission (35047) Ritlecitinib	M/s Pfizer	The firm presented its proposal of Phase III clinical trial with protocol number B7981040 dated 28 July 2022 before the committee. After detailed deliberation, the committee recommended that the firm should submit

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			the complete Phase II clinical trial safety data to CDSCO for review by the committee for taking further action on proposed Phase III clinical trial Protocol.
BA/BE Division			
6.	12-09/2022/BA-BE/Misc-21/DC Roflumilast Cream 0.3%	M/s. Cliantha Research Limited, Ahmedabad-382210	The firm presented its proposal for grant of permission to conduct BA/BE Study of Roflumilast Cream 0.3% for export registration purpose After detailed deliberation,the committee recommended for grant of permission to conduct BA/BE study of Roflumilast Cream 0.3% for export registration purpose with the condition that the firm should specify the maximum application per day/week in Protocol.
Medical Device Division			
7.	IMP/MD/2022/67473 Mucosamin Mouthwash	M/s. Alvita Pharma Private Limited	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 in the country with the condition that the firm should conduct post marketing clinical investigation (Phase IV) of the proposed product in the country on Indian population. Accordingly, the firm should submit post marketing clinical investigation (Phase IV) protocol to CDSCO for further review by the committee.
SND Division			
8.	SND/MA/22/000356 Tofacitinib Gel 2%	M/s Precise Biopharm Pvt. Ltd.	The firm presented the Phase III clinical trial protocol as a part of manufacturing and marketing permission of Tofacitinib Gel 2% for treatment of androgenetic alopecia before the committee for approval. After detailed deliberation, the committee recommended for grant of permission for conduct of Phase III clinical trial as per the protocol presented subject to the condition that the firm should present the data of first 50 patients (equally distributed in each arm) enrolled in the study for review by the

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			committee, prior to further recruitment of the patients in the clinical trial.
9.	SND/MA/22/000320 Tofacitinib Citrate Gel 2% w/w	M/s Synokem Pharmaceuticals	The firm presented the Phase III clinical trial protocol before the committee as per manufacturing and marketing permission of Tofacitinib Ointment 2% for the treatment of treatment of mild to moderate atopic dermatitis (AD). After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase III clinical trial as per the protocol presented subject to the following conditions: 1) Post trial access to standard of care to the patients should be included in the clinical trial protocol for patient's safety. 2) The firm should present the data of first 50 patients (equally distributed in each arm) enrolled in the study for review by the committee, prior to further recruitment of the patients in the clinical trial. 3) The firm should use EASI and SCORAD scales to monitor patients' disease status. Accordingly, the firm should submit revised clinical trial protocol to CDSCO.