Recommendations of the SEC (Dermatology & Allergy) made in its 74th meeting held on 13.10.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/19/000078 Naftifine HCL Gel 2% w/w.	M/s. Hetero Labs Limited	The firm presented the Phase III clinical trial report with proposal for grant of permission to manufacture and market the drug Naftifine HCL Gel 2% w/w before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug Naftifine HCL Gel 2% w/w for the topical treatment of Interdigital Tinea Pedis in the country.
2.	ND/MA/21/000211 Naftifine HCI Cream 2%w/w	M/s. Zydus Healthcare Ltd.	The firm presented the Phase III clinical trial report with proposal for grant of permission to manufacture and market the drug Naftifine HCL 2% w/w Cream before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug Naftifine HCL 2% w/w Cream for the treatment of superficial fungal infection of the skin (Tinea corporis and Tinea cruris) in the country.
3.	ND/MA/21/000192 Naftifine HCI Cream 2%w/w	M/s. Synokem Pharmaceutical Ltd.	The firm presented their proposal for the un-blinding of randomization and interim analysis of data of all patients after completing the visit 4 (i.e. Day 42±3 days/week 6) of the ongoing Phase III Clinical trial with the drug Naftifine HCI Cream 2%w/w. After detailed deliberation, the committee opined that the firm should submit the adequate justification/rationale for the proposed un-blinding of randomization and interim analysis of data before the committee for further consideration of the matter.
Biological Division			
4.	74/Phase IV/ Reliance/16BD Adalimumab Injection	M/s. Reliance Life Sciences Ltd.	The firm presented the clinical study Report (CSR) of the Phase IV clinical trial. After detailed deliberation, the committee noted the results of the study and

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			recommended that the firm should submit revised package insert with the inclusion of the completed Phase-IV trial report and highlighting the warning statement related to tuberculosis and fungal disease. Accordingly, the firm should submit the revised package insert to CDSCO for approval.
5.	BIO/IMP/22/000044 Spesolimab concentrate for solution for infusion 450 mg /vial	M/s.Boehringer Ingelheim India Private Limited	The firm presented their proposal for import and marketing of the drug Spesolimab concentrate for solution for infusion 450 mg/vial along with local clinical trial waiver before the committee. Various regulatory agencies have granted orphan drug designation for Spesolimab for the treatment of generalized pustular psoriasis. The drug is currently approved in USA and Japan on the basis of Phase II study conducted in 53 patients. The committee observed that firm has conducted Phase II global clinical study which did not include Indian patients and the current safety data is not adequate to consider the proposal for local clinical trial waiver. After detailed deliberation, the committee recommended that firm should conduct local clinical trial to prove safety and efficacy of the drug in generalized pustular psoriasis in Indian patients.
6.	BIO/MA/22/000080 Ustekinumab Injection 45 mg/0.5ml PFS	M/s. Reliance Life Sciences Pvt. Ltd.	The firm presented the proposal to manufacture and market Ustekinumab Injection 45mg/0.5ml PFS and vial and 90mg/ml in PFS along with Phase III clinical trial results conducted in the country. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of the drug for treatment of moderate to severe plaque psoriasis in adult patients only subject to the condition that the firm should conduct Phase IV clinical trial in the country. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of marketing approval. Also the firm should submit

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			revised package insert as recommended above.
SND Division			
7.	SND/MA/20/000377 Minocycline HCL Topical Gel 4 %	M/s. Glenmark Pharmaceuticals	The firm did not turn up for presentation.
8.	SND/MA/22/000133 Tofacitinib Ointment 2%	M/s. Intas Pharmaceuticals	In light of earlier SEC recommendation dated on 27-05-2022 the firm presented the study data of first 50 patients enrolled in Phase III clinical trial. Committee noted that there is no safety signal in first 50 patients. After detailed deliberation, the committee recommended that the firm may continue the clinical trial as per approved protocol. The firm should report CDSCO in case of any SAEs related to clinical trial.
9.	SND/MA/19/000077 Tissue Human Amnion Chorion Membrane Dehydrated	M/s. Life Cell	The firm presented the interim results of Phase III clinical study and requested for grant of permission for Dehydrated Human amnion/ chorion tissue allografts and Dehydrated Human amnion/ chorion tissue allografts PHMB. The committed noted that the results of the trial are promising. After detailed deliberation, the committee recommended for grant of permission for Dehydrated Human amnion/ chorion tissue allografts and Dehydrated Human amnion/ chorion tissue allografts PHMB subject to condition that the firm should complete the clinical trial and submit the data to CDSCO for further review by the committee.
GCT Division			
10.	CT/05/22 Online Submission (30192) Ivermectin lotion 0.5%	M/s. Veeda Clinical Research	In light of earlier SEC recommendation dated 12/07/2022, the applicant has presented revised protocol no. 21-VIN-0235, version 03 dated 12/09/2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that the comparator/reference product should be

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			approved licensed product in India.
Medical Device Division			
11.	CI/MD/2022/56988 Nitric Oxide Releasing Collagen Wound Patch	M/s. Cologenesis Healthcare Pvt. Ltd	In light of earlier SEC recommendation dated 06.05.2022, the firm presented their proposal for pivotal clinical investigation of the proposed product in the country. After detailed deliberation, the committee observed that the firm could not submit the rationale & scientific data for using normal dressing as a comparator. Therefore, the firm was advised again to use collagen dressing as a comparator to get more scientific & meaningful comparison, until unless there is rationale otherwise.
12.	CI/MD/2022/61869 Hydrophilic Foam Silver Pad (AgFix Foam)	M/s. Dynamic Techno Medicals Pvt. Ltd	The firm presented their proposal for post marketing Clinical Investigation of the proposed product in the country before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of post marketing clinical investigation of the proposed product in the country on Indian population.