Recommendations of the SEC (Dermatology & Allergy) made in its 11th/24 meeting held on 13.11.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/CT04/FF/2024/44776 Online Submission (44776) Barzolvolimab (CDX-0159)	M/s. PPD Pharmaceutical Development India Private Limited	In light of earlier SEC Recommendation dated 05.09.2024, now the firm presented phase III clinical trial protocol no. CDX0159-13 version no. 1.0 dated 29 March 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
2.	E. 50094 Dupilumab solution for injection 150mg/ml	M/s. Sanofi Healthcare India Private Limited	The firm presented the proposal for the update in prescribing information version dated August 2023 for product Dupilumab solution for injection 150mg/ml pre-filled syringe, based on EMA approval for changes in the section posology & method of administration, special warnings and precautions for use, undesirable effects, description of selected adverse reactions, clinical efficacy etc. After detailed deliberation, the committee recommended for approval of updated prescribing information version dated August 2023 as presented by the firm.
3.	BIO/CT18/FF/2024/42205 Spesolimab solution for injection in Prefilled syringe 150mg/ml	M/s. Boehringer Ingelheim	The firm presented the proposal for the approval of Spesolimab (subcutaneous) solution for injection in pre-filled syringe 150mg/ml for subcutaneous route indicated for the treatment of Generalized pustular psoriasis (GPP) including prevention of flares, in adults with request for waiver of local Phase III clinical trial in India by claiming that Generalized pustular psoriasis (GPP) is rare and life threatening disease. The committee noted that drug Spesolimab concentrate for solution for infusion 450mg/vial (60mg/ml) intravenous route formulation is already approved in India for treatment of flares in adult patients with General Pustular Psoriasis considering as a rare disease. The firm has clarified that proposed drug is meant for prevention of flares of

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			Generalized pustular psoriasis (GPP) in adults. After detailed deliberation, the committee recommended the firm to submit safety and efficacy data in Indian Patients for approval of the Spesolimab solution for Injection for subcutaneous route formulation.
4.	BIO/CT21/FF/2024/4 2025 Usketinumab (Bmab 1200) (r-DNA origin) Injection	M/s Biocon Biologics Limited	The firm presented their proposal for approval of Ustekinumab (Bmab1200) (r-DNA Origin) Bulk, Ustekinumab (r-DNA origin) Injection 45 mg/0.5 mL PFS, 90 mg/mL PFS, 45 mg/0.5 mL vial and 130 mg/26 mL vial to manufacture and market exclusively for export purpose only. The firm has presented the clinical data of Phase I study conducted in UK & Phase III study conducted in EU & US. After detailed deliberation, the committee recommended for the approval of applied products for export purpose by CDSCO as per existing policy.
SND Division			
5.	SND/MA/21/000082 Apremilast Topical Gel 2 % w/w	M/s Aizant Drug Research Solutions	In light of earlier SEC Recommendation dated 14.09.2021, firm presented Phase III clinical trial report results having study protocol no. C20177 version no. 1.0 dated 27.Jun.2021. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Apremilast topical gel 2% w/w for indicated in the mild to moderate plaque psoriasis (Body surface area 2-10%).
6.	SND/MA/20/000377 Minocycline Hydrochloride topical gel 4%	M/s Glenmark Pharmaceuticals Ltd	Firm presented the report of Phase IV clinical trial of the product Minocycline Hydrochloride topical gel 4% in patient with moderate to severe acne vulgaris. After detailed deliberation, committee accepted the safety tolerability and efficacy study as per the condition of marketing authorization granted for the product Minocycline Hydrochloride topical gel 4% in patient with moderate to severe acne vulgaris. The product should be prescribed by the registered Dermatologist only.