Recommendations of the SEC (Dermatology & Allergy) made in its 10th/24 meeting held on 08.10.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/46/24 Online Submission (42650) Amlitelimab	M/s. Sanofi	In light of earlier SEC recommendation 14.05.2024, the firm presented Phase III clinical study protocol No. EFC17600 version no. 1 dated 01.02.24. After detailed deliberation, the committee recommended to grant of permission to conduct the clinical trial with condition that firm should submit to CDSCO separate detailed protocol and procedure to ensure standardized monitoring across all the study sites specifically a detailed document informing investigators about screening for cutaneous/ extracutaneous lymphoma steps of diagnosis and reporting.
2.	CT/141/23 Online Submission (33342) SAR445229 / amlitelimab	M/s. Sanofi	In light of earlier SEC recommendation 11.07.2024, firm presented clinical trial Phase III protocol amendment 01 version 01 dated 20.11.2023 (protocol No. EFC17559). After detailed deliberation, the committee recommended that the safety and efficacy data in adolescent subject shall be submitted for further review by the committee.
3.	CT/119/24 Online Submission (45356) CGB-600 Gel	M/s. Raptim Research Pvt. Ltd.	The firm presented Phase II clinical trial study protocol No.CGB-600-02 version No. 1 dated 29.08.2024. After detailed deliberation, the committee recommended to grant of permission to conduct the clinical trial with condition that the firm should submit histopathological toxicity analysis data from animal studies and ethics committee approval from all sites, especially from Govt. study sites to CDSCO before initiating the trial.
Biological Division			
4.	BIO/CT18/FF/2024/4 4021	M/s. Novartis	The firm presented the proposal for the approval of additional indication of Secukinumab 150mg/ml powder

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Secukinumab 150mg/ml		(lyophilized) for solution for injection in a vial, Secukinumab 150mg/ml solution for injection in prefilled syringe, Secukinumab 150mg/ml solution for injection in pre-filled pen (r-DNA origin) i.e. Treatment of active moderate to severe hidradenitis suppurativa (acne inversa) (HS) in adults with an inadequate response to conventional HS therapy. The firm has presented safety and efficacy results of global clinical trials (SUNRISE and SUNSHINE) conducted in the proposed indication along with Indian subject subset analysis of 16 patients. After detailed deliberation, the committee recommended for the approval of additional indication i.e. Treatment of active moderate to severe hidradenitis suppurativa (acne inversa) (HS) in adults with an inadequate response to conventional HS therapy of Secukinumab 150mg/ml powder (lyophilized) for solution for injection (r-DNA origin) with a condition to conduct Post Marketing Surveillance study in Indian population. The PMS study protocol shall be submitted within 3 months to CDSCO.
SND Division			
5.	SND/CT/24/000041 Clostridium Botulinum neurotoxin type A 50 Unit /100 units	M/s. CliniExperts Services Pvt. Ltd.	The committee noted that the proposed indication Spasticity of lower limb in children and adolescent (age 2 -17) for which firm has submitted phase IV CT protocol is for neurological disorder hence committee advised to present the proposal before SEC (Neurology)
6.	SND/CT/24/000042 Clostridium Botulinum neurotoxin type A 50 Unit /100 units	M/s CliniExperts Services Pvt. Ltd.	The committee noted that the proposed indication Chronic sialorrhea in Adult for which firm has submitted phase IV CT protocol is a neurological disorder, hence committee advised to present the proposal before SEC (Neurology)
7.	SND/CT/24/000035 Ruxolitinib cream 1.5% w/w	M/s Intas Pharmaceuticals Ltd.	The firm presented their proposal for grant of permission to conduct Phase-III clinical trial of Ruxolitinib cream 1.5% w/w along with Phase-III clinical trial

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-III clinical trial of Ruxolitinib cream 1.5% w/w subject to condition that the firm should submit revised clinical trial protocol by incorporating the details of study centers in which the study would be conducted & 50% sites should be from government hospitals and protocol should uniformly include participants aged ≥ 18 years instead of ≥ 12 years in the inclusion criteria to CDSCO. As this is an equivalence study, the document detailing the need for the study and the study design of protocol submitted to CDSCO should also be submitted for review.
8.	SND/MA/21/000544 Tofacitinib Gel 2% w/w	M/s Macleods Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 13.01.2022, the firm presented Phase III clinical trial data of first 50 patients enrolled in the study before the committee. After detail deliberation, the committee opined that, firm should continue with the study as per approved protocol and data for acceptability of the product formulation (gel) from the patient's side should be included and be submitted to CDSCO for further review by the committee.