Recommendations of the SEC (Dermatology & Allergy) made in its 09th/24 meeting held on 05.09.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/101/24 Online Submission (44776) Barzolvolimab (CDX-0159)	M/s PPD Pharmaceutical Development India Pvt. Ltd.	The firm presented Phase III clinical trial study protocol No. CDX0159-13 version No. 1 dated 29 March 2024. After detailed deliberation, the committee opined that there is no Phase-I & Phase-II data for Indian subjects. Further, the committee recommended that the firm should conduct pharmacodynamic studies in Indian subjects (Approx. 50 subjects).
Biological Division			
2.	BIO/CT18/FF/2024/42756 Ustekinumab solution for injection 45mg and 90mg- STELARA	M/s. Johnson & Johnson	The firm presented the proposal for approval of additional indication with waiver of Phase III & Phase IV clinical trial for Ustekinumab solution for injection 45mg and 90mg (Stelara) for indication of Plaque Psoriasis in adults based on the Global clinical data generated from other countries. After detailed deliberation, the committee recommended the firm to submit more safety data of South Asian subjects with Plaque Psoriasis in Adults for further evaluation.
New Drugs Division			
3.	ND/CT/24/000050 Clascoterone Cream 1% w/w	M/s. Om Sai Pharma Pack	The firm presented the proposal of grant of permission to conduct Phase III clinical trial with new drug Clascoterone cream 1% w/w. After detailed deliberation, the committee noted that the presented Phase III clinical trial protocol is not designed adequately. The committee recommended that the firm should made following amendments in proposed Phase III clinical protocol; 1. The comparator arm should be Adapalene instead of Benzoyl Peroxide Gel 2.5 % w/v. 2. Method of contraception should be adequately defined under protocol.

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			3. The evaluator of the study should be blinded w.r.t the study treatment. 4. Duration of follow up should be adequately defined under protocol. 5. Severity of the acne vulgaris with objective score should be defined under protocol. Accordingly, firm should submit revised Phase III clinical trial protocol to CDSCO for further deliberation.
4.	ND/IMP/23/000004 Abrocitinib Tablets 50mg, 100ng & 200mg	M/s. Pfizer Products India Private Limited	The firm presented proposal before the committee for grant of waiver to condition no. 8 mentioned in import and marketing permission of Abrocitinib tablets 50mg, 100mg and 200mg, to conduct of Phase IV clinical trial. The committee noted the recommendations of the SEC dated 14.06.2023, for the subject drug. After detailed deliberation, the committee opined that the firm should conduct the active surveillance study. Accordingly, the firm should submit the study protocol along with parameters for further review by the committee and further consideration of Phase IV clinical trial waiver.
5.	12-1/24-DC(Pt-58) Concentrate of Proteolytic enzyme enriched in Bromelain Topical Gel	M/s. Saara Medical Solution Pvt. Ltd.	The firm presented the request for PMS study waiver and to consider 30 pediatric patients enrolled in India after marketing authorization dated 17-May-2019 and 25 treated patients since September 2023 as PMS requirement for drug Concentrate of proteolytic enzymes enriched in Bromelain before the committee. After detailed deliberation, the committee in its earlier SEC recommendation dated 26.07.2018 recommended for grant of permission to import and market the product subject to condition that the firm should actively follow up 1000 patients as part of PMS. In view of the above, the committee

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			opined that the justification submitted by the firm does not reflect any compelling reason to give waiver for PMS study. Further, the clinical trial has been conducted on limited number of patients and 40% of the burn cases are with deep partial and full thickness thermal burns. Hence, safety data is required on these patients. Accordingly, the committee did not consider the firm's request for waiver of the PMS and reiterated its earlier SEC recommendation dated 26.07.2018.
SND Division			
6.	SND/MA/24/000018 Epinephrine Tartarate Injection 0.15mg/ml & 0.3 mg/ml	M/s. Mylan Laboratories Limited	The proposal was briefed to the experts before the deliberation. The experts opined that proposal may be deliberated with Pulmonologist in presence of Paediatrician and allergy expert. Therefore, the proposal may be put up in the next Pulmonary SEC committee along with Paediatrician and respiratory allergy/ anaphylaxis experts.