Recommendations of the SEC (Dermatology & Allergy) made in its 84th meeting held on 17.08.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT21/FF/2023/35670 Itolizumab Injection25 mg/5 mL	M/s. Biocon Biologics Limited	The firm presented their proposal for approval of subcutaneous route of administration in addition to the approved intravenous route for the product Itolizumab for Injection 100mg/vial for the approved indication i.e., treatment of moderate to-severe chronic plaque psoriasis. After detailed deliberation, the committee recommended that the firm should conduct clinical trial for new route of administration i.e. subcutaneous route to prove that the efficacy of product is similar with the already approved route of administration in the proposed indication. Accordingly, the firm shall submit CT protocol to CDSCO for review by the committee.
SND Division			
2.	SND/MA/23/000154 Tofacitnib Lotion 2% w/v	M/s. Precise Biopharma Pvt. Ltd.	The firm presented their proposal for manufacture and marketing permission of Tofacitnib Lotion 2% w/v (new dosage form) along with Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.
3.	SND/MA/23/000038 Sterile Dehydrated HCM Patch size (12*6 cm^2)	M/s. Lifecell International Pvt. Ltd.	The firm presented their proposal for manufacture and marketing permission of Sterile Dehydrated Human Chorion Membrane (Patch size 12 x 6 cm^2) additional pack size along with Justification for waiver of clinical trial study before the committee. The committee noted that Sterile Dehydrated Human Chorion Membrane with Patch size 5 x 5 cm^2 is already approved in the country since 15.11.2022. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Sterile

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			Dehydrated Human Chorion Membrane (Patch size 12 x 6 cm^2) additional pack size with waiver of CT and BE study subject to condition that the firm should submit PSUR data annually for next 4 years.
4.	SND/CT/23/000030 Isotretinoin Oral Solution 32 mg/ml & Isotretinoin Capsules 24 mg	M/s. IDRS Labs Pvt. Ltd.	The firm presented the proposal to conduct relative bioavailability study of Isotretinoin Oral Solution 32 mg/ml equivalent to 24 mg (24mg/0.75ml) & Isotretinoin Capsules 24 mg along with bioavailability study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the bioavailability study subject to condition that the firm should exclude the patient having family history of coronary hypertension, hyperlipedemia, and arthrosclerosis or any other abnormality.
GCT Division			
5.	CT/108/20 Online Submission (21453) Efgartigimod	M/s. PPD	The firm presented protocol amendment for Protocol No.:ARGX-113-1905, version 3.0 dated 05.Sep.2022 along with data as recommended to be submitted in earlier SEC meeting dated 15.03.2023 before the committee. After detailed deliberation, the Committee recommended the approval of protocol amendment as presented by the firm.
6.	CT/107/20 Online Submission (25968) ARGX-113 (Efgartigimod) PH20 SC	M/s. PPD	The firm presented protocol amendment for protocol No.:ARGX-113-1904,version 5.0 dated 09.Dec.2022 before the committee. After detailed deliberation, the Committee recommended the approval of protocol amendment as presented by the firm.
7.	CT/160/22 Online Submission (35047) Ritlecitinib	M/s. Pfizer	In light of earlier SEC recommendation dated 17.05.2023, the firm presented the justification and proposal for the grant of Phase III Clinical trial permission Protocol No.:B7981040 dated 28 July 2022 before the committee.

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			After detailed deliberation, the committee again recommended that the firm should generate the Phase II clinical data on 20 Indian subjects for dose selection of proposed IMP as in presented Phase II clinical trial data, no Indian subjects were involved and study disease is very heterogeneous. Accordingly, clinical trial protocol should be submitted for review and the data generated in Phase II data should be presented before the SEC for further consideration for grant of permission to conduct the proposed Phase III clinical trial.
8.	CT/125/21 Online Submission (25477) Dupilumab	M/s. Sanofi	The firm presented protocol amendment for Protocol No.:EFC16724, amendment 03 version 1 dated 01.Mar.2023 before the committee After detailed deliberation, the committee recommended that the proposal should be re-deliberation after including two ENT surgeons in SEC.
9.	CT/177/22 Online Submission (26730) ADL-018	M/s. Kashiv Bio-Science	The firm presented protocol amendment in protocol No. :KBS/OMA/01, version 5.0 dated 14 June 2023 to increase additional number of subjects upto 280 from India before the committee. After detailed deliberation, the committee recommended for approval to increase additional number of subjects upto 280 from India subject to the condition that the study design shall be similar to the Innovator.