Recommendations of the SEC (Dermatology & Allergy) made in its 01st /25 meeting held on 16.01.25 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/24/24 Online Submission (36278) BP11 Omalizumab	M/s CurateQ Biologics Private Limited	The firm presented protocol amendment 1.1, Version 2.1 (India) dated 14-Nov-2024, protocol no. BP11-301. After detailed deliberation, the committee recommended for approval of protocol amendment to increase the number of subjects from 200 to 300 in the study as presented by the firm.
2.	CT/147/24 Online Submission (46710) AC-203 Diacerein 1% Ointment	M/s Veeda Clinical Research Limited	The firm presented phase II/III clinical study protocol number: AC-203-EBS-007 version 3 dated 16-Jun-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/153/24 Online Submission (46903) SAR445229 amlitelimab	M/s Sanofi Healthcare India Private Limited	The firm presented phase II/III clinical study protocol no. LTS17367 amendment number 05 version 1 Dated 16 Aug 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
4.	E-62152 Guselkumab solution for injection 100 mg	M/s. J&J Pvt. Ltd	The firm presented the proposal for amendment in the warning statement for the drug product Tremfya® Guselkumab solution for injection 100mg (in single use pre-filled syringe) & Guselkumab solution for injection 100mg (in single use pre-filled pen) approved for the indication of Active Psoriatic Arthritis from "To be sold by retail on the prescription of a Registered Rheumatologist only" to "To be sold by retail on the prescription of a Registered Rheumatologist and Registered Dermatologist only". After detailed deliberation, the committee recommended for approval of proposed addition of 'Registered Dermatologist' in

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			the warning statement of the drug product for the indication of Active Psoriatic Arthritis.
SND Division			
5.	SND/MA/23/000011 Tofacitinib Ointment 2% w/w.	M/s.Lyka Labs Private Limited	The firm presented active PMS study protocol No. SCR/001/TFC/2023, version No.1 dated 30.11.2023 before the committee. After detailed deliberation, the committee recommended to conduct Active PMS study as per protocol presented by the firm.