Recommendations of the SEC (Dermatology & Allergy) made in its 80th meeting held on 13.04.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/IMP/22/000073 Clostridium Botulinum Neurotoxin type A 50 & 100 Units	M/s Clini Experts Services Pvt. Ltd.	The firm presented its proposal for import & marketing of Clostridium Botulinum Neurotoxin Type A 50.000 Units and Clostridium Botulinum Neurotoxin Type A 100.000 Units for following indications i.e 1) Spasticity of the lower and upper limb in children and adolescents (age 2-17 years) 2) Chronic sialorrhea in adults , 3) Chronic sialorrhea in children and adolescents (age 2-17years) , 4) Lateral periorbital lines (crows feet) and 5) Horizontal fore head lines. After detailed deliberation the committee recommended that proposal should be re-deliberated in next meeting along with the Pediatrician and Neurologist as experts.
2.	SNDMA/23/000040 Tofacitinib film forming lotion 2% w/v	M/s Hetero Health care Ltd	The firm did not turn up for presentation.
3.	SND/MA/23/000019 Dimetindene Maleate Gel 0.100% w/w	M/s Sotac Pharmaceuticals Ltd	The firm did not turn up for presentation.
4.	SND/MA/22/000133 Tofacitinib Ointment 2%	M/s Intas Pharmaceuticals	The firm presented the proposal for manufacturing and marketing of Tofacitinib Ointment 2% w/w along with the results of Phase III clinical trial before the committee. After detailed deliberation, the committee recommended that the results of Phase III clinical trial might be re-deliberated in presence of other experts who are involved in deliberation for approval of clinical trial protocol.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
5.	CT/177/22 Online Submission (35345) ADL-018 Omalizumab	M/s Kashiv Bioscience	The proposal was deferred for the next meeting.
6.	CT/146/22 Online Submission (34845) LOU064 (Remibrutinib)	M/s Novartis	The firm presented the proposal of grant of Phase III clinical trial permission with Protocol No. CLOU064A2303B; Version: 00 dated 30-May-2022. After detailed deliberation, the committee recommended that the firm should submit complete safety data of ongoing study till date for further review by the committee to allow extension of the current study.
7.	CT/160/22 Online Submission (35047) Ritlecitinib	M/s Pfizer	The proposal was deferred for the next meeting.
Medical Device Division			
8.	CI/MD/2023/81032 Gel Implant (Brand Name: Los Deline™)	M/s JCP International Pvt. Ltd.	The proposal was deferred for the next meeting.