Recommendations of the SEC (Dermatology & Allergy) made in its 71st meeting held on 12.07.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/18/00045 Desonide Ointment 0.05 %	M/s Encube	The firm presented their proposal of Phase IV clinical trial waiver for Desonide ointment 0.05%. After detailed deliberation, the committee did not agree for Phase IV clinical trial waiver.
2.	SND/MA/22/000020 Tofacitinib Ointment 2% w/v	M/s Lyka Labs	The firm presented their proposal for some changes in approved protocol of Phase III clinical trial of Tofacitinib Ointment 2% w/w (Protocol No. LL/CT/Phase III/03/21, Version No. 1, Dated 30.09.21) before the committee. After detailed deliberation, the committee opined that the justifications provided by the firm for proposed changes in already approved protocol are not adequate. Accordingly, the committee did not recommend for the proposed changes.
GCT Division			
3.	CT/04/22 Dupilumab	M/s. Sanofi	The firm presented their Phase II/III Clinical trial protocol no:EFC16723, amendment 01 (Version 1) dated 08 July 2021. After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions: 1. The applicant should conduct first part A of the study and submit its data for further review by the committee for further continuation of the trial (Part B). 2. In case of treatment failure, the applicant should pay all expenses including cost of nasal surgery to the trial subjects. 3. Gold Quantiferon TB test should be done at screening visit & end of treatment visit. 4. In informed consent document, all SAEs and AEs of test drug should be elaborated.

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4.	CT/05/22 Ivermectin lotion 0.5%	M/s. Veeda Clinical Research	In light of earlier SEC recommendation dated 08.06.2022, the firm presented Phase III clinical trial protocol before the committee with justification for conduct of proposed study in India. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that the study should be conducted in three arms-test, reference (approved drug in India) and placebo in 2:2:1ratio. Accordingly, the applicant should submit revised protocol to CDSCO for approval.
5.	CT/125/21 Dupilumab	M/s. Sanofi Healthcare	The firm presented their amended clinical trial protocol 02, Version number 1 dated 23Nov 2021. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
Medical Device Division			
6.	CI/MD/2022/59520 Semipermeable Waterproof Plastic Wound Dressing With Silver	M/s. Dynamic Techno Medicals Pvt. Ltd.	The firm presented their proposal for post marketing clinical investigation of the proposed product before the committee. The committee observed that protocol presented by the firm was not clear. After detailed deliberation, the committee recommended that the firm should present detailed clinical investigation protocol with assessment criteria of safety & efficacy, wound measurement assessment. Committee also recommended that presenting team should have technical person with clinical background. Accordingly, the firm should submit and present detailed clinical investigation protocol for further review of the committee.
7.	MD/Post Appr/2021/7209 Haemostatic Powder (HaemoCer™ PLUS Haemostatic powder)	M/s Morulaa Health Tech Pvt Ltd	The firm didn't turn up for presentation.

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8.	CI/MD/2022/56347 Artificial Skin (Bio-inspired Bi-layer Polymeric Hybrid Scaffold)	AIIMS, New Delhi	The firm didn't turn up for presentation.
Additional Proposal-SND Division			
9.	SND/MA/21/000490 Tofacitinib Ointment 2% w/v	M/s. Optimus	The firm presented their proposal of Phase III clinical trial protocol of Tofacitinib Ointment 2% w/v for androgenic alopecia without any pre-clinical and published clinical data about proposed indication. After detailed deliberation, the committee opined that the firm did not present any scientific rationality data and supportive published literature for the proposed indication. Accordingly, the committee recommended that the firm should submit pre-clinical data, published clinical data and scientific rationality with respect to proposed indication for further consideration.