

Recommendations of the SEC (Dermatology & Allergy) made in its 70th meeting held on 08.06.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/IMP/21/000046 Tildrakizumab injection 100 mg/ml	M/s Sun Pharma	The firm did not turn up for presentation.
SND Division			
2.	SND/CT/22/000033 Diperoxochloric acid topical solution 0.29mg/ml	M/s Centaur Pharmaceuticals	<p>The firm presented the proposal for conduct of Phase III clinical trial for Diperoxochloric acid topical solution 0.29mg/ml.</p> <p>After detailed deliberation, the committee recommended as follows: 1) The firm should submit detailed justification for proposed indication along with preclinical data and published literature. 2) The submitted Phase III protocol is inadequate with respect to inclusion, exclusion criteria, subgroup analysis, control arm, sample size and respective subgroups.</p> <p>Accordingly, the firm should revise clinical trial protocol and submit to CDSCO for further deliberation by the committee in presence of plastic surgeon.</p>
3.	SND/MA/18/00045 Desonide Ointment 0.05%	M/s Encube Ethical	The firm did not turn up for presentation.
GCT Division			
4.	CT/05/22-DCGI Ivermectin lotion 0.5% (Test product of Sponsor) in the treatment of human head lice infestation.	M/s Veeda	<p>The firm presented Phase III clinical trial protocol no. 21-VIN-0235 version 01 dated 25/10/2021 before the committee.</p> <p>After detailed deliberation, the committee did not recommend for grant of permission to conduct the clinical trial as the applicant has not justified the conduct of proposed clinical trial in India only as a part of global development.</p>
Medical device Division			

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5.	MD/Post Appr/2021/7892 Hyaluronic Acid 15mg + Lidocaine Hydrochloride 3mg(Juvederm VOLBELLA with Lidocaine)	M/s Allergan healthcare india private ltd	The firm presented their proposal for post approval change in indication before the committee. After detailed deliberation, the committee recommended for grant of approval for proposed indication subject to the condition that IFU should contain data related to how much to be injected in one sitting.
6.	MD/Post Appr/2021/7209 Haemostatic Powder (HaemoCer™ PLUS Haemostatic powder)	M/s Morulaa Health Tech Pvt. Ltd.	The firm did not turn up for presentation.