

Recommendations of the SEC (Dermatology & Allergy) made in its 69th meeting held on 06.05.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000133 Tofacitinib Ointment 2%	M/s. Intas Pharma	<p>The firm presented the Phase III clinical trial protocol before the committee as part of manufacturing and marketing permission of Tofacitinib Ointment 2%.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase III clinical trial as per the protocol presented subject to the following conditions:</p> <ol style="list-style-type: none"> 1) Post trial access to standard of care to the patients should be included in the clinical trial protocol for patient's safety. 2) The firm should present the data of first 50 patients (equally distributed in each arm) enrolled in the study for review by the committee, prior to further recruitment of the patients in the clinical trial. 3) More study sites from government hospitals geographically distributed in the country should be included in the study. <p>Accordingly, the firm should submit revised clinical trial protocol to CDSCO.</p>
Medical Device Division			
2.	CI/MD/2022/56988 Nitric Oxide Releasing Collagen Wound Patch (ColoNox)	M/s. Cologenesis healthcare Pvt ltd	<p>The firm presented their protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct pivotal clinical investigation with the proposed product vs collagen dressing (in the two arms) instead of normal dressing. Further, if patient does not recover in the course of the trial, the applicant should take care of it and provide medical management and compensation as per the rules.</p> <p>Accordingly, the firm should submit the amended protocol to CDSCO.</p>

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3.	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.