

Recommendations of the SEC (Dermatology & Allergy) made in its 73rd meeting held on 14.09.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/CT/22/000033 Diperoxochloric acid Topical solution 0.29 mg/ml	M/s. Centaur Pharmaceuticals	In light of earlier SEC recommendation dated 08.06.2022, the firm presented revised Phase III clinical trial protocol for conduct of study in multiple indications along with the justification for proposed indications, preclinical data and published literature. After detailed deliberation, the committee did not recommend for conduct of the Phase III clinical trial as per protocol presented. The committee advised that the firm should submit separate clinical trial protocols for each indication.
Medical Device Division			
2.	MD/Post Appr/2021/7209 Haemostatic Powder (HaemoCer™ PLUS Haemostatic powder)	M/s. Morulaa Health Tech Pvt. Ltd.	In light of earlier SEC recommendation dated 18.08.2022, the firm presented their proposal for post approval change in indication before the committee. After detailed deliberation, the committee recommended that the firm should conduct Pivotal Clinical Investigation of the proposed device for additional indication in the country on Indian population. Accordingly, the firm should submit clinical investigation protocol to CDSCO for further review by the committee.
3.	CI/MD/2022/59520 Semipermeable Waterproof Plastic Wound Dressing with Silver (Sterizone)	M/s. Dynamic Techno Medicals Pvt. Ltd.	In light of earlier SEC recommendation dated 12.07.2022, the firm presented their proposal for post marketing clinical investigation of the proposed device in the country before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of post marketing clinical investigation of the proposed device in the country.
SND Division			
4.	SND/CT/19/000052	M/s. Shilpa Medicare	The firm presented Phase II clinical trial study results of Dutasteride Topical Solution 0.01% w/v, 0.02% w/v and

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	Dutasteride Topical Solution 0.01% w/v, 0.02% w/v and 0.05% w/v		0.05% w/v before the committee. After detailed deliberation, the committee opined that the presented Phase II CT report is adequate.