

Recommendations of the SEC (Dermatology & Allergy) made in its 67th meeting held on 15.03.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT/22/000025 Til-drakizumab	M/s. Sun Pharma	The firm presented clinical trial protocol for Phase III clinical trial before the committee. After detailed deliberation, the committee recommended that the firm should present more data on unmet medical need for the drug in the country along with the rationale for proposed trial design for further review by the committee.
FDC Division			
2.	FDC/MA/20/000091 Metronidazole IP 2% w/w + Mupirocin IP 2% w/w Ointment	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm didn't turn up for presentation.
GCT Division			
3.	CT/13/22 Online Submission (30393) dated 04/02/2022 ASLAN004	M/s. IQVIA	The firm presented clinical trial protocol for Phase IIb clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the protocol presented.
Medical Device Division			
4.	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.