

Recommendations of the SEC (Dermatology & Allergy) made in its 68th meeting held on 19.04.2022 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/22/000008 Trifarotene 50 µg/g cream	M/s Galderma India Pvt Ltd.,	<p>The firm presented their proposal for Import and marketing of the drug Trifarotene 50 µg/g cream along with local clinical trial waiver before the committee.</p> <p>The committee noted that the drug is already approved in US, Germany, U.K & Canada. Also, the drug is an Orphan drug and there is an unmet medical need in the country for the proposed indication.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market the drug with waiver of local clinical trial subject to the condition that the firm should conduct Phase IV clinical trial for which protocol should be submitted within 3 months of approval of the drug for review by the committee.</p>
2.	ND/MA/22/000057 Fosravuconazole L- Lysine Ethanolate Capsule 169.1 mg	M/s Dr. Reddy Lab	<p>The firm presented their proposal along with the Phase III CT protocol and justification for BE study waiver before the committee.</p> <p>After detailed deliberation, the committee agreed to the waiver of BE study and recommended for grant of permission to conduct the Phase III CT as per the proposed protocol.</p>
SND Division			
3.	SND/CT/22/000020 Tofacitinib Ointment 2%	M/s Lyka Labs	<p>The firm presented the Phase III CT protocol along with the results of animal toxicity study before the committee for approval.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of the Phase III CT study as per the protocol presented subject to the condition that atleast 50% of the CT study sites should be government hospitals geographically distributed in the country.</p>
4.	12-130/2016-DC (Pt- Galderma-SND)	M/s Galderma Pharma	In light of recommendations of earlier SEC meeting dated 17.01.2020, the firm

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Clostridium Botulinum Type-A Toxin Hemagglutinin Complex Injection 300 units/vial		presented the revised active pharmacovigilance plan for the drug product to capture the adverse events of all patients treated with the drug who are not included in Phase IV clinical trial. After detailed deliberation, the committee recommended for approval of the revised active pharmacovigilance plan.
Medical device Division			
5.	IMP/MD/2021/43978 Biological Matrix for Prepectoral Breast Surgery (Braxon [®]), Biological Matrix for Breast Surgery (Native [®])	M/s LEAP BIOSURGICAL LLP	In light of earlier SEC recommendations dated 15.02.2022, the firm presented their proposal for grant of permission to import and market the proposed product before the committee. After detailed deliberation, the committee recommended for grant of permission to import and market the proposed product in the country with the condition that the firm should conduct Phase IV post marketing clinical investigation of the proposed product in the country. Accordingly, the firm should submit Phase IV post marketing clinical investigation protocol to this office within 3 months from the date of approval for committee review.
6.	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.