

Recommendations of the SEC (Dermatology & Allergy) made in its 65th meeting held on 13.01.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/21/000211 Naftifine Hydrochloride Cream USP 2% w/w	M/s. Zydus Healthcare Limited	<p>The firm presented the proposal for manufacturing and marketing of the drug Naftifine Hydrochloride cream 2% w/w along with Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented subject to the following conditions:</p> <ol style="list-style-type: none"> 1. The firm should submit clinical photograph of the study population. 2. Microbial culture should be conducted for initial, end of treatment and follow up for the same study population. 3. Accordingly, revised CT protocol should be submitted to CDSCO before initiation of the study.
2.	ND/IMP/21/000192 Naftifine Hydrochloride cream 1% and 2% USP	M/s. Synokem Pharmaceuticals	<p>The firm presented the proposal for manufacturing and marketing of the drug Naftifine Hydrochloride cream 1% & 2% w/w alongwith Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented subject to the following conditions:</p> <ol style="list-style-type: none"> 1. The firm should submit clinical photograph of the study population. 2. Microbial culture should be conducted for initial, end of treatment and follow up for the same study population. 3. Accordingly, revised CT protocol should be submitted to CDSCO before initiation of the study <p>The committee also recommended that the firm should submit data related to the drug product formulation as per the requirements of ND & CT Rules 2019.</p>

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3.	ND/CT/21/000101 Abrocitinib 100 and 200 mg tablet	M/s. Pfizer	<p>The firm presented the proposal for conduct of Phase IIIb/IV CT protocol for the treatment of moderate to severe atopic dermatitis in adults and adolescents 12 years and older before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as Phase III for the treatment of moderate to severe atopic dermatitis in patients of age 18 years and above subject to condition that the firm should, in addition, perform the study assessment through “SCORAD” scoring and photography should be utilized to capture accurate images of initial status, end of treatment outcome and follow up status of all study population.</p> <p>Further, the committee opined that the proposal for pediatrics/adolescent need to be deliberated in next SEC (Dermatology & Allergy) meeting along with pediatric dermatologist, pediatrician and orthopedic surgeon (pediatric) for further review.</p>
SND Division			
4.	SND/MA/21/000001 Baricitinib Tablets 2/4 mg	M/s Eli Lilly	<p>In light of recommendations of earlier SEC meeting dated 12.08.2021, the firm presented their proposal for reconsideration of clinical trial waiver.</p> <p>After detailed deliberation, the committee reiterated its earlier recommendation that “the firm should conduct a clinical study on clinically significant number of patients by excluding the patients with past history or with concurrent TB. Further, photographs should be documented during the conduct of the study.</p> <p>Accordingly, the firm should submit the Phase III clinical trial protocol on statistically significant number of patients to CDSCO for further review by the committee.</p>
5.	12-124/2017-DC (Pt-Novalead-SND) Esmolol Hydrochloride	M/s Novalead Pharma	The firm presented the Phase III clinical trial report for Esmolol Hydrochloride 14.00% w/w.

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	14.00% w/w		After detailed deliberation, the committee opined that the clinical trial report should be re-deliberated in presence of experts from Plastic surgery and Diabetologist.
6.	12-115/2017-DC (Pt-Synokem- SND) Itraconazole Sustained Release 400mg tablets	M/s Synokem Pharma	The firm did not turn-up for presentation.
7.	SND/MA/21/000544 Tofacitinib Gel 2%	M/s Macloeds Pharmaceuticals	<p>The firm presented the Phase III clinical trial protocol as a part of manufacturing and marketing permission of Tofacitinib Gel 2% before the committee for approval.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of Phase III clinical trial as per the protocol presented subject to the condition that 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.</p>
FDC Division			
8.	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			
9.	CT/125/21 EFC16724	M/s. Sanofi	<p>The firm presented the clinical trial Phase III protocol no EFC16724 version 1.0 dated 30/03/2021 before the committee.</p> <p>Assessment of risk versus benefit to the patient- The drug is already approved in the country, its safety profile may justify the conduct of the proposed trial.</p> <p>Innovations Vs existing therapeutic option- The primary objective of the study is to evaluate the ability of Dupilumab to reduce the need for rescue therapy with systemic corticosteroids (SCS) or surgery of allergic fungal Rhinosinusitis in patients with AFRS who previously have had surgery for</p>

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			<p>Rhinosinusitis.</p> <p>Unmet medical need in the country- The test drug may be better treatment option in patients with Allergic Fungal Rhinosinusitis.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study with the condition that in case of treatment failure, the applicant should pay all expenses including cost for nasal surgery to the subjects. Accordingly, the applicant should submit undertaking to CDSCO and also include the same statement in the Informed Consent Document.</p>