

Recommendations of the SEC (Dermatology & Allergy) made in its 08th/24 meeting held on 07.08.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/139/23 Online Submission (34081) Remibrutinib	M/s. Novartis Healthcare Private Limited	The firm presented protocol amendment version 02 dated 19 Apr 2024 protocol no. CLOU064A2304. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Medical Devices Division			
2.	MFG/MD/2020/2410 8 Nitric oxide releasing Collagen wound patch (Brand Name: ColoNox)	M/s. Cologenesis Healthcare Pvt. Ltd.	The firm presented the Clinical Investigation report carried on the proposed product i.e. Nitric oxide releasing Collagen wound patch as per the protocol approved by the Central Licensing Authority on the Indian population, before the committee. After detailed deliberation, the committee satisfied with the data presented and recommended for the grant of permission to manufacture the said product with the indication that it should be intended for the treatment of Diabetic wounds, in the country for its commercialization.
SND Division			
3.	SND/MA/23/000231 Minoxidil tablets 2.5mg	M/s. Akums Labs Limited	The firm presented the proposal for grant of permission to manufacture and marketing of Minoxidil Tablets IP 2.5mg along with justification for waiver of both BE study and local clinical trial before the committee. The firm has informed that Minoxidil tablets 2.5mg, 5mg and 10mg monograph is available in IP-2010 as antihypertensive and Minoxidil is a BCS class-I drug. Further, Minoxidil tablets 2.5mg is not approved anywhere in the world for the proposed indication. After detailed deliberation, the committee noted that the justification presented by the firm for the waiver of local clinical trial is not found adequate. Therefore, the committee recommended to conduct

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			Phase III clinical trial for which the firm should submit clinical trial protocol to CDSCO for further review by the committee.
4.	SND/MA/23/000154 Tofacitinib Lotion 2% w/v	M/s. Precise Biopharma Pvt. Ltd.	In light of the earlier SEC recommendation dated 17.08.2023 the firm presented Phase III clinical trial report of Tofacitinib Lotion 2%w/v before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Tofacitinib Lotion 2%w/v with subject to condition that: <ol style="list-style-type: none"> 1. The label and prescribing information shall mention following in boxed warning “treatable body surface area should not be more than 20%” 2. Proposed formulation shall be indicated for “treatment of mild to moderate atopic dermatitis (AD) in patients 18 years & above having flare up of disease with treatable body surface area not more than 20%”
5.	SND/MA/24/000018 Epinephrine Tartarate Injection 0.15mg/ml & 0.3 mg/ml	M/s. Mylan Laboratories Limited	The firm did not turn up for presentation.
New Drugs Division			
6.	ND/MA/24/000066 Clascoterone Cream 1%	M/s. Dr. Reddy’s Laboratories Limited	The firm presented its proposal for manufacturing and marketing of the drug Clascoterone Cream 1% w/w along with Phase III Clinical Trial protocol before the committee. After detailed deliberation, the committee opined that the firm should submit the revised Phase III Clinical Trial protocol as a comparative study with standard of care and also, the firm should include laboratory analysis of hormonal levels at the inclusion of all the patients,

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			as the proposed drug is a hormone receptor blocker.
7.	ND/IMP/24/000047 Clascoterone Cream 1%	M/s. Sun Pharmaceuticals Pvt. Ltd.	<p>The firm presented its proposal for import and marketing of the drug Clascoterone Cream 1% w/w, along with Phase III Clinical Trial protocol before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should submit the revised Phase III Clinical Trial protocol as a comparative study with standard of care and also the firm should include laboratory analysis of hormonal levels at the inclusion of all the patients, as the proposed drug is a hormone receptor blocker.</p>
8.	ND/CT/24/000037 Clascoterone with minoxidil and Clascoterone with latanoprost in solution form	M/s. Glenmark Pharmaceuticals Ltd.	<p>The firm presented the proposal for grant of permission to conduct the Phase II clinical trial study for new drug Clascoterone 7.5% w/w and Minoxidil 5% w/w Topical Solution and Clascoterone 7.5% and Latanoprost 0.03% Topical Solution, vide protocol no. GPL/CT/2024/001/II, Version 1.0, Dated-14th May 2024, before the committee.</p> <p>After detailed deliberation, the committee recommended for conduct of Phase II Clinical Study as per the presented protocol.</p> <p>Further, the firm should spell out the protocol to the patient who suffers an adverse event and how they will be managed and it should be uniform across all the centers. The trials sites should be geographically distributed with 50% Govt. institutes throughout the country.</p>
9.	12-1/24-DC (Pt-58) Concentrate of Proteolytic enzyme enriched in Bromelain Topical Gel	M/s. Saara Medical Solution Pvt. Ltd.	The firm did not turn up for presentation.

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FDC Division			
10.	FDC/MA/22/000353 Miconazole Nitrate IP 2% w/w + Luliconazole IP 1% w/w + Preservative Methyl Paraben IP 0.15% w/w Topical Cream	M/s. Zenvision Pharma Ltd.	<p>In light of the earlier SEC recommendation dated 15.12.2022 and 26.07.2023, the firm presented their proposal along with the point wise justification including Dermal toxicity study report as well as In-vitro antifungal (mixed culture) efficacy study using ZOI test.</p> <p>After detailed deliberation the committee opined that:</p> <ol style="list-style-type: none"> 1. The firm was unable to present any scientific rationality or essentiality for combination of two azole antifungals working at the same step of Ergosterol synthesis in the fungal cell and its significant benefits. 2. Combination of two azole drugs in the proposed FDC may lead to cross resistance. 3. The occurrence of mixed fungal infections are very rare and the firm was unable to provide supportive literature/data to justify the proposed indication. 4. The curative anti-fungal property of Miconazole is not mediated through steroid receptor as claimed by the firm in their presentation. 5. The product is not approved internationally. 6. There is no unmet need for proposed FDC. <p>In view of above, the committee did not recommend for approval of the proposed FDC.</p>