

Recommendations of the SEC (Dermatology & Allergy) made in its 03rd/24 SEC meeting held on 14.03.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/160/22 Online Submission (35047) Ritlecitinib	M/s. Pfizer	<p>In light of earlier SEC recommendation dated 17.08.2023, the firm presented the justification and Phase III clinical trial protocol before the committee, vide protocol No. B7981040, and final protocol dated 28 July 2022.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the phase III clinical trial with subject to the following conditions:</p> <ol style="list-style-type: none"> 1. Test for tuberculosis should be done at the time of screening, at 6 month, & at end of therapy, as treatment duration is 52 weeks. 2. Adolescents (12 to <18 years of age) should be excluded from the study. Accordingly the patients above 18 years should be recruited in the study. 3. Risk Assessment tuberculosis to be mentioned. 4. In rescue section –mention data analysis plan to be adopted by the study- including patients who drop out. <p>(Dr. Davinder Prasad did not participate in the deliberation).</p>
2.	CT/01/24 Online Submission (41231) Remibrutinib (LOU064)	M/s. Novartis	<p>The firm presented Phase III clinical trial protocol No. CLOU064M12301, version 00 (original protocol) dated 27 June 2023.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as presented by the firm.</p>
3.	CT/24/24 Online Submission (41957) BP11 Omalizumab	M/s. Curateq Biologicals	<p>The firm presented Phase III clinical trial protocol No. BP11-301, and protocol amendment 1, version 2.0, dated 17 Jan 2024.</p> <p>After detailed deliberation, the committee recommended for grant of permission to</p>

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			conduct the Phase III clinical trial as presented by the firm. (Dr. Davinder Prasad did not participate in the said proposal)
BA/BE Division			
4.	File No. 12-09/2024/BA-BE/MISC-16/DC BABE/CT05/FF/2023/40624 Chlorpheniramine Maleate + Ibuprofen + Phenylephrine HCl Granules(4+200+10) mg	M/s. Dr. Reddy's Laboratories Limited,8-2-337, Road No. 3, Banjara Hills, Telangana (India) -500034	The firm presented protocol No. 095-2, version No.1, dated 13.09.2023 and protocol No. 096-2, version No.1, dated 13.09.2023. After detailed deliberation, the committee recommended the firm should conduct the study as per the presented protocol.
5.	File No. 12-09/2024/BA-BE/MISC-18/DC BABE/CT05/FF/2023/41230 Epinephrine Nasal Spray, 2 mg per spray (T1 and T2)	M/s. Actimus Biosciences Private Limited, Visakhapatnam (India) - 530003	The firm presented protocol No. EPIN-153-23, version No. 00, dated 07.12.2023. After detailed deliberation, the committee did not recommend the proposed study as the applied test product dosage strength is not approved anywhere in the world and the prototype of proposed reference formulation (nifty) is under review by the concerned regulatory authority (USFDA).
SND Division			
6.	SND/MA/23/000287 Ozenoxacin Cream 2% w/w (Additional Strength)	M/s. Om Sai Pharma Pack	The firm presented the proposal for manufacture and marketing of Ozenoxacin cream 2% w/w (Additional Strength) along with justification for Phase-III clinical trial waiver before the committee. After detailed deliberation, the committee opined that the firm should conduct comparative Phase-III clinical trial with specific indication i.e. superficial skin bacterial infection (impetigo, folliculitis). Accordingly, firm should submit Phase-III clinical trial protocol to CDSCO for further review by the committee.
7.	12-16011(11)/12/2024-e-office	M/s. Glenmark Pharmaceuticals	In light of earlier SEC recommendations dated 31.05.2018 & 08.07.2021. Now,

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	Apremilast Tablets 10mg, 20mg, 30mg	Limited	<p>firm presented Phase-IV clinical trial study report before the committee. Firm has informed that 169 patients were enrolled and 161 patients were taken for safety consideration and 112 patients were taken for efficacy evaluation.</p> <p>After detailed deliberation, the committee opined that the firm should submit complete Phase-IV trials in 300 patients as per approved protocol and submit the same to CDSCO for further review by committee.</p>
8.	SND/MA/23/000152 Triamcinolone Acetonide Ointment USP 0.025% & 0.5%	M/s. Macleods Pharma Ltd.	<p>The firm presented the proposal for manufacture and marketing of Triamcinolone Acetonide ointment USP 0.025% & 0.5% (Additional dosage form) along with justification for Phase-III clinical trial waiver before the committee.</p> <p>The firm informed that Triamcinolone Acetonide ointment USP 0.025% & 0.5% not yet approved in the country. However, similar formulation Triamcinolone Acetonide cream 0.1% w/v is approved by CDSCO on 22.12.2020.</p> <p>After detailed deliberation, the committee opined that the firm should submit more clinical data of proposed lower strength along with specific use in children and adult population for review by the committee.</p>
9.	SND/MA/23/000239 Naftifine HCl Solution 1 %	M/s. Biodeal Pharmaceuticals Limited	<p>The firm presented their proposal for manufacture and marketing of Naftifine HCl topical solution 1% (Additional dosage form & indication) along with justification for Phase-III clinical trial and bioequivalence study waiver before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should submit more clinical relevance data along with supporting documents/literature to support the waiver of clinical trial or submit Phase-III clinical trial protocol to</p>

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			CDSCO for further review by the committee.
New Drugs Division			
10.	ND/CT/23/000092 Crisaborole Ointment 2%	M/s. Pfizer	In line with the condition for the permission for the import and marketing of the drug Crisaborole ointment 2%, the firm presented Phase IV clinical trial protocol for drug Crisaborole ointment 2% before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct Phase IV clinical trial as per protocol presented.