

**Recommendations of the SEC (Dermatology & Allergy) made in its 81<sup>st</sup> meeting held on 17.05.2023 at CDSCO (HQ), New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drug Division</b>			
1.	ND/CT18/FF/2023/ 35856  Abrocitinib Tablets 50mg, 100mg, 200mg	M/s. Pfizer Products India Pvt. Ltd.	The proposal was deferred for next meeting.
<b>SND Division</b>			
2.	SND/MA/23/000040  Tofacitinib film forming lotion 2 % w/w	M/s. Hetero Health Care Ltd.	The proposal was deferred for next meeting.
3.	SND/MA/22/000020  Tofacitinib Ointment 2% w/w	M/s. Lyka Labs Ltd.	<p>The firm presented the Phase III clinical trial results with request for grant of permission for manufacturing and marketing of Tofacitinib Ointment 2% w/w along with the following data as per SEC recommendation dated 15.03.2023.</p> <ol style="list-style-type: none"> <li>1. Enrolment details of first 50 subjects in the clinical trial.</li> <li>2. Enrolment details of subsequent subjects in the clinical trial after approval of study continuation permission issued to the firm.</li> <li>3. Number of subjects categorized in mild and moderate groups based on disease progression.</li> <li>4. Sleep quality measurement of enrolled subjects in details.</li> <li>5. Number of subjects enrolled in the study with lesion on faces.</li> </ol> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Tofacitinib Ointment 2% w/w for the treatment of mild to moderate atopic dermatitis (AD) in patients 18 years &amp; above having flare up of disease after verification of raw data of the clinical trial from randomly selected clinical trial sites by CDSCO.</p> <p>Further, the committee also opined that</p>

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			<p>the firm should include-</p> <ol style="list-style-type: none"> <li>1. The following Warning: The drug should not be used for more than three months continuously as safety data for only 4 weeks is established in clinical trial.</li> <li>2. The drug should be sold by retail on the prescription of Dermatologist only.</li> <li>3. The firm should also conduct active post marketing surveillance study to assess long term safety of the drug.</li> </ol> <p>Accordingly, the firm should submit protocol to CDSCO for further review by the committee.</p>
4.	SND/MA/22/000133  Tofacitinib Ointment 2% w/w	M/s. Intas Pharma	<p>The firm presented the proposal for grant of permission for manufacturing and marketing of Tofacitinib Ointment 2% w/w for the treatment of mild to moderate atopic dermatitis (AD) along with Phase III clinical trial results.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Tofacitinib Ointment 2% w/w for the treatment of mild to moderate atopic dermatitis (AD) in patients 18 years &amp; above having flare up of disease.</p> <p>Further, the committee also opined that the firm should include-</p> <ol style="list-style-type: none"> <li>1. The following Warning: The drug should not be used for more than three months continuously as safety data for only 4 weeks is established in clinical trial.</li> <li>2. The drug should be sold by retail on the prescription of Dermatologist only.</li> <li>3. The firm should also conduct active post marketing surveillance study to assess long term safety of the drug.</li> </ol> <p>Accordingly, the firm should submit protocol to CDSCO for further review by the committee.</p>
5.	SND/MA/23/000019  Dimetindene Maleate	M/s. Sotac Pharmaceuticals Pvt. Ltd.	The proposal was deferred for next meeting.

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	Gel 0.100% w/w		
6.	SND/IMP/22/000073  Clostridium Botulinum Neurotoxin Type A 50.000 Units and Clostridium Botulinum Neurotoxin Type A 100.000 Units	M/s. Clini Experts Services Private Limited	<p>The firm presented the proposal for import &amp; marketing of Clostridium Botulinum Neurotoxin Type A 50.000 Units and Clostridium Botulinum Neurotoxin Type A 100.000 Units for following indications i.e</p> <ol style="list-style-type: none"> <li>1) Spasticity of the lower and upper limb in children and adolescents (age 2-17 years)</li> <li>2) Chronic sialorrhea in adults.</li> <li>3) Chronic sialorrhea in children and adolescents (age 2-17 years),</li> <li>4) Lateral periorbital lines (crows feet) and</li> <li>5) Horizontal forehead lines</li> </ol> <p>along with the results of global post marketing safety data in adults as well as pediatric patients with request for local clinical trial waiver.</p> <p>The committee noted that the Clostridium Botulinum Neurotoxin Type A is approved for above indication in well regulated countries.</p> <p>After detailed deliberation, the committee recommended for grant of permission for import and marketing of Clostridium Botulinum Neurotoxin Type A 50.000 Units and Clostridium Botulinum Neurotoxin Type A 100.000 Units for following indications i.e</p> <ol style="list-style-type: none"> <li>1) Spasticity of the lower and upper limb in children and adolescents (age 2-17 years)</li> <li>2) Chronic sialorrhea in adults ,</li> <li>3) Chronic sialorrhea in children and adolescents (age 2-17 years).</li> <li>4) Lateral periorbital lines (crows feet) and</li> <li>5) Horizontal forehead lines.</li> </ol> <p>The committee also recommended that firm should conduct Phase IV clinical trial for the above mentioned indications, Accordingly, Phase IV clinical trial protocol should be submitted to CDSCO within 3 months from the date of approval for further review by the committee.</p>

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
7.	SND/MA/23/000111  Tofacitinib Gel 2% w/w	M/s. Precise Biopharma Pvt. Ltd.	The proposal was deferred for next meeting.
8.	12-54/2023-DC (Pt-Misc/SND) Triamcinolone Actinoid Cream 0.1% w/w	M/s. Abbott Healthcare	The proposal was deferred for next meeting.
9.	SND/MA/23/000105  Human Amnion Chorion Membrane with Polyhexamethylene Biguanide Powder Particulates 2% w/w	M/s. Lifecell International Pvt. Ltd.	The proposal was deferred for next meeting.
<b>FDC Division</b>			
10.	FDC/MA/23/000107  Hydrous Benzoyl Peroxide IP 3.75% + Clindamycin Phosphate IP 1.2% Topical Gel	M/s. Precise Biopharma Pvt. Ltd.	The proposal was deferred for next meeting.
11.	FDC/MA/23/000016  Halobetasol propionate USP 0.1mg + Tazarotene 0.45mg topical lotion	M/s. Sun Pharmaceuticals	The proposal was deferred for next meeting.
12.	FDC/MA/23/000001  Latanoprost 0.03% w/v + Finasteride 0.1% w/v + Minoxidil 5% w/v topical solution	M/s. Apodictic	The proposal was deferred for next meeting.
<b>GCT Division</b>			
13.	CT/177/22 Online Submission (35345)  ADL-018 Omalizumab	M/s. Kashiv Bioscience	The firm presented the proposed Phase III biosimilar trial protocol No. KBS/OMA/01, version 3.0 dated 18-Oct-2022.  After detailed deliberation, the committee recommended for grant of permission for

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			<p>conduct of the proposed trial with the following conditions:</p> <ol style="list-style-type: none"> <li>1) The use of anti-histaminic should be narrowed down to the use of levocetirizine only. Subject who failed to respond to the double dose of the levocetirizine should only be qualified for the inclusion in the proposed biosimilar trial.</li> <li>2) Inclusion criteria for the age of proposed trial subject should be 18years to 60 years.</li> <li>3) The firm should only recruit a maximum of up to 200 subjects from the country.</li> <li>4) There should be 50% site from Govt. hospitals</li> <li>5) The Investigator at all proposed trial sites should be well-experienced dermatologists.</li> </ol>
14.	<p>CT/160/22 Online Submission (35047)</p> <p>Ritlecitinib</p>	M/s. Pfizer	<p>In light of the earlier SEC recommendation dated 15.02.2023, wherein the SEC recommended that the firm should submit the complete Phase II Clinical Trial Safety data for review by the committee, the proposal of the firm for Phase III Clinical Trial vide Protocol No. B7981040, Final Protocol, 28-July-2022 was re-deliberated wherein the firm presented Phase II Clinical Trial Safety data before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should generate the Phase II clinical data on 20 Indian subjects for dose selection of proposed IMP as in presented Phase II clinical trial data, no Indian subjects were involved and study disease is very heterogeneous. The said generated Phase II data should be presented before the SEC for further consideration for grant of permission to conduct the proposed Phase III Clinical trial.</p>
15.	<p>CT/27/23 Online Submission (36577)</p> <p>Amlitelimab</p>	M/s. Sanofi	<p>The firm presented the proposed Phase II clinical trial protocol no. LTS17789, version no. 1 dated 31-Oct-2022 before the committee.</p> <p>The committee noted the following observations which are to be included in</p>

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>the proposed protocol or clarification to be provided by the firm:</p> <ol style="list-style-type: none"> <li>1) The firm should define and include the diagnosis of AD as inclusion criteria for the trial and the method should be standardized and reproducible at all the trial sites.</li> <li>2) The sub-group analysis to be presented vis-à-vis their inclusion and exclusion criteria for the proposed indication.</li> <li>3) The rescue treatment is mostly dependent on the investigator's discretion and hence it should be more detail with most clinical criteria's.</li> <li>4) The plan to handle the adverse events (AEs) management in the trial subjects.</li> </ol> <p>After detailed deliberation, the committee recommended that the firm should present the reply/clarification before the committee and should submit the revised protocol to CDSCO for further review by the committee.</p>
<b>Medical Device Division</b>			
16.	CI/MD/2023/81032  Gel Implant (Brand Name: Los Deline™)	M/s. JCP International Private Limited	<p>The firm presented the proposal for conduct of pivotal clinical investigation of the proposed product Gel Implant (Brand Name: Los Deline™) in the country on Indian population before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of Pivotal Clinical Investigation of the proposed product Gel Implant (Brand Name: Los Deline™) in the country on Indian population with the following condition:</p> <ol style="list-style-type: none"> <li>1. The firm should include more clinical study sites.</li> <li>2. 50% of the total clinical study sites should be from Government institutes and 50% of total enrollment of patients should be from such government sites.</li> </ol>

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17.	CI/MD/2021/38809  Ablation Device Cryotherapy (Brand Name: HYDROZID)	M/s. Bibawo Medical Private Limited	The firm did not turn up for presentation.
<b>Cosmetic Division</b>			
18.	COS/MISC/57/22 Online File No. (COS/Form42/FR/2019/9025)  Microneedle Eye Patch	M/s. Sparash Pharma International Pvt. Limited	The proposal was deferred for next meeting.