

**Recommendations of the SEC (Dermatology & Allergy) made in its 63<sup>rd</sup> meeting held on 17.11.2021 at CDSCO HQ New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>SND Division</b>			
1.	SND/MA/21/000469 Ozenoxacin Lotion 2%	M/s. Optimus Pharma	<p>The firm presented the proposal for manufacturing and marketing of Ozenoxacin Lotion 2% along with phase III clinical trial protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial with the condition that photographic evidences shall be preserved. Blinding procedure may be adopted during conduct of clinical trial.</p>
2.	SND/MA/21/000173 Itraconazole 100mg Capsule (Supra bio available formulation)	M/s. Pure & Cure	<p>In light of earlier recommendations of SEC (Dermatology and Allergy) held on 14.09.2021, the firm presented package insert of Itraconazole 100 mg capsule (Supra bioavailable).</p> <p>After detailed deliberation, the committee recommended that the firm may now launch the product in the market as per the manufacturing permission granted by CDSCO.</p> <p>However, in the package insert the firm should include caution as mentioned in condition number (ix) of the manufacturing permission i.e “Itraconazole Capsules 100 mg (Supra bioavailable formulation) is not interchangeable or substitutable with other Itraconazole products due to the differences in dosing between Itraconazole Capsules 100 (Supra bioavailable formulation) and other Itraconazole product”.</p>
3.	12-124/2017-DC (Pt-Novalead-SND) Esmolol Hydrochloride gel 14.00% w/w	Novalead Pharma Pvt Ltd	<p>In light of earlier recommendations of SEC meeting held on 13.10.2021, the firm presented their justification against repeating the study with well defined criteria for choosing the superficial ulcers.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the final phase III CT study report for further review by the committee.</p>

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<b>GCT Division</b>			
4.	CT/122/21 Online Submission (28285)  Remibrutinib	M/s. Novartis Healthcare	<p>The firm presented the proposal for phase III clinical trial protocol vide no. CLOU064A2302, Version 00, Dated 19 May 2021 before the committee.</p> <p><b>Assessment of risk versus benefit to the patients-</b> The safety profile of the study drug from various preclinical toxicology studies and clinical studies presented before the committee.</p> <p><b>Innovation vis-a-vis existing therapeutic option:</b> There is need for new treatment options for CSU patients inadequately controlled by H1-antihistamines. Remibrutinib demonstrated significant clinical efficacy and a fast onset of action in the treatment of patients with CSU across a range of doses compared to placebo is a promising therapeutic concept for the treatment of CSU.</p> <p><b>Unmet medical need-</b> There is a high unmet medical need for new treatment options for CSU patients inadequately controlled by H1-antihistamines.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the phase III clinical trial.</p> <p>Prof. (Dr.) Sanjeev Handa did not participate in the deliberation.</p>
5.	CT/125/21 Online Submission (28349)  SAR231893 Dupilumab/Dupixent	M/s. Sanofi	<p>The firm presented Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended that the proposed IP Dupilumab is approved for atopic dermatitis and proposed indication is allergic fungal rhinosinusitis in the proposed trial.</p> <p>Hence, the committee recommended that the proposal should be deliberated in the presence of an ENT Specialist.</p>
6.	CT/121/21 Online Submission (28286)	M/s. Novartis Healthcare	<p>The firm presented the proposal for phase III clinical trial protocol vide no. CLOU064A2301, Version 00, Dated 19 May 2021 before the committee.</p>

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	Remibrutinib		<p><b>Assessment of risk versus benefit to the patients-</b> The safety profile of the study drug from various preclinical toxicology studies and clinical studies presented before the committee.</p> <p><b>Innovation vis-a-vis existing therapeutic option:</b> There is need for new treatment options for CSU patients inadequately controlled by H1-antihistamines. Remibrutinib demonstrated significant clinical efficacy and a fast onset of action in the treatment of patients with CSU across a range of doses compared to placebo is a promising therapeutic concept for the treatment of CSU.</p> <p><b>Unmet medical need-</b> There is a high unmet medical need for new treatment options for CSU patients inadequately controlled by H1-antihistamines.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the phase III clinical trial.</p> <p>Prof. (Dr.) Sanjeev Handa did not participate in the deliberation.</p>
<b>Medical Device Division</b>			
7.	IMP/MD/2021/39227  Cutaneous Cryogenic Spray(Endwarts Freeze &Endwarts Freeze XL)	M/s. Mylan Pharmaceuticals Private Limited	<p>In light of earlier SEC recommendations dated 14.09.2021, the firm presented their proposal before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market the proposed product in the country with the conditions that</p> <ol style="list-style-type: none"> <li>1. The firm needs to conduct (Phase IV) post market clinical investigation in the country and protocol needs to be submitted to the committee for further review.</li> <li>2. The package insert should clearly specify in bold letters that “This product should not be used on face and on the skin.”</li> <li>3. The product can be bought only with the prescription of specialist.</li> </ol>

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8.	IMP/MD/2021/43978  Biological Matrix for Prepectoral Breast Surgery (Braxon®), Biological Matrix for Breast Surgery (Native®)	M/s. Leap Biosurgical LLP	<p>The firm presented their proposal for grant of permission to import and market the proposed product in the country before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct clinical investigation of the proposed device on Indian population.</p> <p>Accordingly, the firm should submit the protocol for clinical investigation for further review.</p>
9.	CI/MD/2021/44655  Theruptor Sterile Barrier Wound Dressing	M/s. Care Now Medical Pvt. Ltd.	<p>The firm presented their protocol for pivotal clinical investigation before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should submit amended protocol considering the following :</p> <ol style="list-style-type: none"> <li>1. Patient population is not uniform and therefore it needs to be objectified.</li> <li>2. Mode and timing of randomization, grouping, and type of allocation should be uniform.</li> <li>3. The firm should improvise the technology for measurement of wound depth.</li> <li>4. Outcome evaluation should be more objectified.</li> <li>5. Photographic evaluation needs to be incorporated in the protocol.</li> </ol>