

**Recommendations of the SEC (Dermatology & Allergy) made in its 66<sup>th</sup> meeting held on 15.02.2022 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drug Division</b>			
1.	ND/CT/21/000101  Abrocitinib 100/200 mg tablet	M/s. Pfizer limited	In light of earlier recommendation of the committee dated 13.01.2022, the firm presented their proposal before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per the protocol presented.
<b>SND Division</b>			
2.	12-124/2017-DC (Pt-Novalead-SND)  Esmolol Hydrochloride 14.00% w/w	M/s. Novalead Pharmaceuticals	In light of earlier recommendations of the SEC meeting dated 13.01.2022, the firm presented the results of clinical trial report before the committee.  After detailed deliberation, the committee noted the results of the Phase III clinical trial and also recommended the following: <ol style="list-style-type: none"> <li>1. The firm should submit separate application for manufacture and market of the drug for the indication superficial diabetic foot ulcers to CDSCO as per the requirements of the New Drugs and Clinical Trials Rules, 2019.</li> <li>2. The firm should include information/warning regarding diabetic control, precautions in patients with cardiovascular involvements etc. in the proposed package insert while submitting the above application.</li> </ol> <p>Further, the committee opined that as and when the application is submitted by the firm the proposal needs to be deliberated in presence of experts from Cardiology, Plastic surgery and Diabetology.</p>
<b>GCT Division</b>			
3.	CT/57/19 Online Submission (12822)  Baricitinib	M/s. Eli Lilly	In light of earlier SEC recommendation dated 13.10.2021, the firm presented their response before the committee.  After detailed deliberation, the committee opined that the firm should

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			<p>submit following information:</p> <p>1) The firm should submit more safety data for inclusion of pediatric patients in lower age group (6-11years of age).</p> <p>2) Safety data for 2-6 years of age group is grossly inadequate; hence, the firm should submit more safety data for proposed age group for further review by the committee in presence of Pediatrician.</p>
<b>Medical Device Division</b>			
4.	CI/MD/2021/44655  Theruptor Sterile Barrier Wound Dressing	M/s. Care Now Medical Private Ltd.	<p>In light of earlier SEC recommendations dated 17.11.2021, the firm presented their protocol for pivotal clinical investigation before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical investigation of the proposed device in the country as per the protocol presented.</p>
5.	CI/MD/2021/48568  Theruptor Sterile Barrier Wound Dressing	M/s. Care Now Medical Private Ltd.	<p>The firm presented their protocol for clinical investigation before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical investigation of the proposed device in the country as per the protocol presented .</p>
6.	IMP/MD/2021/49794  Temporary Wound Dressing (BIOBRANE)	M/s. Smith & Nephew Healthcare Pvt. Ltd.	<p>The firm presented their proposal for grant of permission to import and market the proposed product 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.</p>
7.	IMD/Post Appr/2021/7209  Haemocer Plus	M/s. Morulaa Healthcare Pvt. Ltd	The firm didn't turn up for presentation.
8.	IMP/MD/2021/43978  Biological Matrix for Prepectoral Breast Surgery (Braxon®), Biological Matrix for	M/s. Leap Bio Surgical LLP	<p>In light of earlier SEC recommendations, the firm presented their proposal for grant of permission to import and market the proposed product before the committee.</p> <p>The committee opined that the firm should submit the detailed clinical data</p>

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	Breast Surgery (Native®)		for review by the committee.
<b>BA/BE Division</b>			
9.	12-09/2022/BA-BE/Misc-01/DC (Application No. BABE/CT05/FF/2021 /28496)  Cetirizine Di-hydrochloride Gel, 5%	Dr. Reddy's Laboratories Limited, Hyderabad-500034	The firm presented their proposal for grant of permission to conduct BA-BE study before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the protocol presented.