

**Recommendations of the SEC (Dermatology & Allergy) made in its 61<sup>st</sup> meeting held on 14.09.2021 at CDSCO HQ New Delhi:**

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>SND Division</b>			
1.	SND/CT/20/000001 Cross linked Sodium Hyaluronate injection 24mg/0.8ml	M/s Bio-tech vision care	In light of recommendation of SEC dated 15-04-2021 the firm submitted safety data and justification for conduct of Phase IV clinical trial. The committee observed that the protocol submitted by the firm is a comparative clinical trial. Hence the terminology of the clinical trial is required to be changed to Phase III from Phase IV. After detailed deliberation the committee recommended that the firm should submit comparative physical properties of reference and test products and submit the protocol for Phase III clinical trial for further deliberation by the committee.
2.	SND/MA/21/000082 Apremilast topical gel 2%	M/s Aziant Drugs	In light of recommendation of SEC held on 09-06-2021, the firm presented the revised Phase III Clinical trial protocol with inclusion of the third arm with SOC. After detailed deliberation committee recommended for grant of permission to conduct the Phase III clinical trial as per protocol presented.
3.	SND/MA/21/000077 Itraconazole Capsule 100mg ( Modified Dosage Form – Supra bioavailable)	M/s Intas Pharmaceuticals	The firm presented the proposal for manufacturing and marketing of Itraconazole Capsule 100mg (Supra bioavailable) along with the results of the BE Study. After detailed deliberation the committee recommended for grant of permission for Itraconazole Capsule 100mg (Supra bioavailable) for the indication for already approved Itraconazole Capsule 50 mg (Suprabioavailable) subject to condition that firm should present Package Insert mentioning the effect of Proton pump inhibitors, oral antacids, alcohol and other drugs interactions which may affect the bioavailability of the drug etc. before launch of the product in the market. The package insert should also include details of results of the BE study conducted in the country.
4.	SND/MA/21/000173 Itraconazole Capsule 100mg ( Modified Dosage Form	M/s Pure and Cure	The firm presented the proposal for manufacturing and marketing of Itraconazole Capsule 100mg (Supra bioavailable) along with the results of the

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	– Supra bioavailable)		BE Study. After detailed deliberation the committee recommended for grant of permission for Itraconazole Capsule 100mg (Supra bioavailable) for the indication for already approved Itraconazole Capsule 50 mg (Supra bioavailable) subject to condition that firm should present Package Insert mentioning the effects of Proton pump inhibitor, oral antacids, alcohol, other drugs interactions which may affect the bioavailability of the drug etc. before launch of the product in the market. The package insert should also include details of results of the BE study conducted in the country.
5.	12-82/2017-DC (Pt Cadila-SND) Calcipotriol / AKV ANO 50 ug/gm Cutaneous solution	M/s Cadila Pharmaceuticals	The firm did not turn up for the presentation.
<b>FDC Division</b>			
6.	FDC/MA/21/000155 Clindamycin phosphate 1.2% USP + Benzoyl peroxide 5% USP topical gel	M/s. EncubeEthicals Pvt. Ltd.	The firm did not turn up for presentation.
7.	FDC/CT/21/000015 Betamethasone dipropionate EP 0.6430mg+ Calcipotriol anhydrous mcg EP50mcgcutaneous spray	M/s. Cadila Pharmaceuticals Ltd.	In light of earlier recommendation of the SEC dated 16.03.2021, the firm presented the revised Phase III Protocol along with the detailed justification for waiver of dermal toxicity.  After detailed deliberation the committee recommended for grant of permission for conducting the proposed Phase III Clinical trial.
8.	FDC/CT/21/000045 Minoxidil 5%/5% + Finasteride 0.25%/0.5% Topical lotion	M/s. New India Biopharma	The firm presented their proposal before the committee and after detailed deliberation, the committee opined that: 1. The firm is required to provide detailed justification w.r.t waiver of dermal toxicity study. 2. Proposed higher strengths of Finasteride are not approved anywhere else in the world. 3. The firm did not present any rationale/ proof of concept studies indicating that proposed higher strengths of FDC are therapeutically advantageous without local side effects.

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			In view of above, the committee recommended that firm should present their proposal considering above points again before the committee for further consideration.
<b>GCT Division</b>			
9.	CT/90/18 Online Submission (11985) Dated 09/07/21 Secukinumab	M/s. Novartis	The firm presented proposal for clinical trial protocol amendment version #02 dated 08.01.2021. After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial as per the presented protocol amendment, However the committee also opined that for consideration of marketing authorization of the drug in the country more clinical data is required to be generated in the country.
10.	CT/108/20 Online Submission (11888) Dated 28/06/21 ARGX-113 (Efgartigimod)	M/s. PPD	The firm presented the proposed amendment to the study protocol no. ARGX-113-1904, Version 3.0 (Amendment 2) dated 18-MAY-2021 before the committee. After detailed deliberation, the Committee recommended for approval of the proposed protocol amendment.
<b>Medical Device Division</b>			
11.	IMP/MD/2021/39227 Cutaneous Cryogenic Spray(Endwards Freeze &Endwards Freeze XL)	M/s Mylan Pharmaceutical s Private Limited	The firm presented their proposal for permission to import and market the proposed products before the committee.  After detailed deliberation the committee recommended for grant of permission to import and market the proposed product in the country subject to the condition that 1. The firm needs to conduct (Phase IV) post market clinical investigation in the country and protocol for the same needs to be submitted within 2 months of approval of the product. 2. IFU needs to be presented before the committee before launch of the product in the country.
12.	MD/Post Appr/2021/7209 Haemostatic Powder (HaemoCer™ PLUS Haemostatic powder)	M/s Morulaa Health Tech Pvt Ltd	The firm presented their proposal for post market change in indication before the committee.  After detailed deliberation the committee recommended that firm should submit following data to CDSCO for further review by the committee:

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			<p>1. Regulatory and marketing status of the proposed product with respect to new indication in other countries.</p> <p>2. Animal study data, clinical data of the product with respect to the new indication generated in other countries.</p>
13.	CI/MD/2021/43127 Collagen Dressing	M/s CBCC Global research LLP	<p>The firm presented their proposal for post market clinical investigation before the committee.</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the post market (Phase IV) clinical investigation of the proposed products in the country subject to the following conditions:</p> <p>1. There should be 3 months follow up after closure of wound.</p> <p>2. The report of the study should be submitted to CDSCO for review by the committee.</p>