

Recommendations of the SEC (Dermatology & Allergy) made in its 82nd meeting held on 14.06.2023 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/21/000101 Abrocitinib 100/200mg tablet	M/s. Pfizer Limited	<p>The firm presented its application for grant of permission to import Abrocitinib tablets 50mg, 100mg and 200mg for sale or for distribution along with Phase III clinical study data to the committee.</p> <p>After detailed deliberation, the committee recommended for grant of import permission for sale or for distribution of Abrocitinib tablets 50mg, 100mg and 200mg indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable subject to following conditions:</p> <ol style="list-style-type: none"> 1) The firm should conduct Phase IV clinical trial for which the firm should submit Phase IV clinical trial protocol within 3 months of approval of the drug for review by the committee. 2) The firm should submit periodic safety update reports (PSURs) as per Rules.
SND Division			
2.	12-54/2023-DC (Pt-Misc/SND) Triamcinolone Actinoid Cream 0.1% w/w	M/s. Abbott Healthcare Pvt. Ltd.	<p>The firm presented the proposal for amendment in CT-23 for Triamcinolone Acetonide cream 0.1 % w/w for change in warning from “To be sold by retail on the prescription of dermatologist only” to “To be sold by retail on the prescription of dermatologist and physician only” along with justification and rationality, before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should submit revised PI of the drug product with respect to duration of the treatment, defined anatomical area of the treatment etc., for further evaluation by the committee.</p>

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
3.	SND/MA/23/000105 Human Amnion Chorion Membrane with Polyhexa Methylene Biguanide Powder 2 % w/w	M/s. Life Cell International Pvt. Ltd.	<p>The firm presented the proposal for manufacture and marketing permission for Human Amnion Chorion Membrane with Polyhexamethylene Biguanide powder particulates 2.000 % w/w for the treatment of acute and chronic non-healing wounds, along with international approval status, clinical trial waiver justification and some in-vitro data, before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct comparative Phase III clinical trial with available standard care/approved product/placenta membrane or both as comparator. Accordingly, the firm should submit Phase III clinical trial protocol for further review by the committee.</p>
4.	SND/MA/23/000111 Tofacitinib Gel 2% w/w	M/s. Precise Biopharm Pvt. Ltd	<p>The firm presented the proposal of manufacture and marketing permission for Tofacitinib gel 2% for the treatment of Vitiligo (new dosage form & new indication) along with Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended that firm should conduct Phase III clinical trial which should be three arm study for Tofacitinib gel 2%w/w vs standard of care treatment and placebo control with the ratio of 2:2:1. Accordingly, the firm should submit the revised Phase III clinical trial protocol for further review by the committee.</p>
5.	SND/MA/23/000040 Tofacitinib film forming Lotion 2% w/w	M/s. Hetero Health Care Limited.	<p>The firm presented the proposal for manufacturing and marketing permission for Tofacitinib film forming lotion 2% w/w (new dosage form) along with Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial with condition that the firm should keep photographic records for disease progression of subjects from enrolment to end of the study.</p>

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6.	SND/MA/23/000038 Sterile Dehydrated Human Chorion membrane (Patch size 12*6cm2)	M/s. Lifecell International Private Limited	The proposal was deferred for next SEC meeting.
7.	SND/MA/21/000544 Tofacitinib Ointment 2% w/w	M/s. Macleods Pharmaceuticals Limited	<p>The firm presented the proposal for manufacture and marketing permission for Tofacitinib ointment 2%w/w for the treatment of patients with mild-to-moderate atopic dermatitis along with Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should submit revised clinical trial protocol after inclusion of following points for further review by the committee:</p> <ol style="list-style-type: none"> 1. The firm should keep photographic records of all infected area for disease progression of subject during enrolment and end of the study. In addition, the firm should perform the study assessment through SCORED scoring as well as EASI scale. 2. The treatment duration in the study should be preferably twelve weeks. 3. Study sites should be geographically distributed and 50% sites should be from government hospital. 4. During the study, the subject should be allowed to take antihistamine along with the study drug and maintain the patient log of antihistamine use. 5. Patient should be encouraged to maintain visual analog scale of itching, roughness, redness and severity.
8.	SND/MA/23/000019 Dimetindene Maleate Gel 0.100% w/w	M/s. Sotac Pharmaceuticals Ltd.	The firm presented the proposal of manufacture and marketing permission for Dimetindene Maleate gel 0.100 % w/w for the treatment of insect bites, sunburn, short-term relief of pruritus associated with dermatoses, urticaria and superficial skin burns (first degree) alongwith international approval status of the drug before the committee.

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			After detailed deliberation, the committee recommended that firm should submit following data for further consideration by the committee: <ol style="list-style-type: none"> 1. Drug-drug interaction data. 2. Trans-cutaneous drug absorption data. 3. Drug sensitization data.
FDC Division			
9.	FDC/IMP/23/000001 Latanoprost + Finasteride + Minoxidil (0.03% w/v+ 0.1%w/v+5%w/v) Topical Solution	M/s. Apodictic	In light of earlier SEC recommendation dated 15.03.2023, the firm presented the scientific rationale as well as dermal toxicity study data before the committee. After detailed deliberation, the committee recommended that the firm should conduct a comparative, randomized, three arm Phase III clinical trial. Accordingly, the firm should submit Phase III clinical trial protocol for review by the committee.
10.	FDC/MA/23/000016 Halobetasol propionate USP + Tazarotene (0.1mg+0.45mg)topi cal Lotion	M/s. Sun Pharmaceuticals	In light of earlier SEC recommendation dated 15.03.2023, the firm presented the justification for repeat dose PK study waiver as well as justification for Phase III clinical trial waiver before the committee. After detailed deliberation, the committee did not consider the firm's justification for repeat dose PK study waiver as well as Phase III clinical trial waiver and reiterated earlier SEC recommendation dated 15.03.2023. Accordingly, PK study protocol and Phase III clinical trial protocol should be presented before the committee for review.
11.	FDC/MA/22/000353 Luliconazole1% + Miconazole2% I.P. Cream	M/s. Zenvision Pharma Ltd.	The proposal was deferred for next SEC meeting.
12.	FDC/MA/23/000107 Hydrous Benzoyl Peroxide IP 3.75% +	M/s. Precise Biopharma Pvt. Ltd.	The proposal was deferred for next SEC meeting.

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	Clindamycin Phosphate IP 1.2% Topical Gel		
GCT Division			
13.	CT/108/20 Online Submission (21453) Efgartigimod	M/s. PPD	The proposal was deferred for next SEC meeting.
14.	CT/13/22 Online Submission (23034) ASLAN004	M/s. IQVIA	The proposal was deferred for next SEC meeting.
Medical Device Division			
15.	CI/MD/2021/38809 Ablation Device Cryotherapy (Brand Name: HYDROZID)	M/s. Bibawo Medical Private Limited	The proposal was deferred for next SEC meeting.
16.	CI/MD/2020/31181 Soft tissue regeneration matrix (Brand Name: Serimat®)	M/s. Serigen Mediproducts Private Limited	The proposal was deferred for next SEC meeting.
Cosmetics Division			
17.	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 SEC meeting.