

Recommendations of the SEC (Dermatology & Allergy) made in its 04th/24 meeting held on 16.04.2024 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/27/23 Online Submission (31561) Amlitelimab	M/s. Sanofi	The firm presented protocol amendment 02, version 01 dated 29 November 2023 protocol No. LTS17789. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. (Note: The committee did not consider the enrollment of 7 adolescent subjects in the study because the firm did not present the study results of adult subjects and regulatory approval from other participating countries before the committee).
2.	CT/168/23 Online Submission (41129) Bedaquiline	M/s. J&J	In light of earlier SEC recommendation dated 11.01.24, the firm requested to waive off condition to include more than 5 skin lesions which are smear positive in inclusion criteria. (Phase 3 clinical study protocol No. TMC207LEP3001 version No. original dated 09 November 2023). After detailed deliberation, the committee accepted the firm request to waive off condition "to include more than 5 skin lesions which are smear positive in inclusion criteria".
Biological Division			
3.	BIO/CT21/BO/2023/ 39673 Adalimumab 40 mg/0.4 ml solution for injection	M/s. Shilpa Biologicals Private Limited	The firm presented the proposal for approval of following additional indications by the way of extrapolation in line with the indications of innovator product. <ol style="list-style-type: none"> 1. Psoriasis 2. Paediatric plaque psoriasis 3. Hidradenitis suppurativa (HS) The firm has also presented the first PSUR data generated. After detailed deliberation, the committee recommended for approval of following additional indications in adult population- <ol style="list-style-type: none"> 1. Psoriasis

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			2. Hidradenitis suppurativa (HS) For approval of paediatric plaque psoriasis indication the committee recommended that proposal may be deliberated in the presence of Paediatrician.
BA/BE Division			
4.	File No. 12-09/ 2024/ BA-BE /MISC-23/DC BABE/CT05/FF/2023 /41023 Epinephrine Sublingual Tablets 40 mg	M/s. Lambda Therapeutic Research Limited, Ahmedabad - 382481	The firm presented the protocol No. 0357-23 ver. 1.0 dated 28.11.2023 for conducting BA/BE study for export purpose only. After detail deliberation, the committee recommended for the grant of permission to carry out BA/BE study for export purpose only, subject to condition to include the additional sample collection time point at 01 min and 02 min. Accordingly, the firm shall submit the revised protocol to CDSCO for taking further necessary action.
5.	File No. 12-09/2024/ BA-BE/MISC-08/DC BABE/CT05/FF/2023 /40000 Isotretinoin Capsules USP 60 mg	M/s. Aurobindo Pharma Ltd, Hyderabad- 500038	The firm presented the revised protocol No.: 239-23 ver. 2 dated 02.03.2024 and 240-23 ver. 2 dated 02.03.2024 before the committee. After detail deliberation, the committee recommended for the grant of permission to carry out BA/BE study for export purpose only
Medical Device Division			
6.	IMP/MD/2023/99038 PROFHILO Body - 3.2% 48 mg (H-HA) + 48mg (L-HA)/3 ml Hyaluronic acid sodium salt	M/s. Alma Medical Pvt. Ltd.	The firm presented proposal for grant of permission to import the medical device PROFHILO BODY - 3.2%; 48 mg (H-HA) + 48mg (L-HA)/3 ml Hyaluronic acid sodium salt which is manufactured by M/s Ibsa Farmaceutici Italia S.r.l., Via Martiri di Cefalonia 2, 26900 Lodi (LO), Country: Italy. The firm presented the summary of clinical study data generated on total 121 patients and regulatory status in other countries including UK, EU. The firm has also presented the published data

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			<p>supporting the clinical safety, performance & effectiveness of the device. The said device is approved in UK since year 2022 including EU.</p> <p>After detailed deliberation, and based on the documents presented, the committee recommended for consideration of the proposal. However, the firm shall submit the protocol to conduct Post marketing Clinical Investigation so as to have Clinical Follow-Up data in the Indian population.</p>
SND Division			
7.	SND/CT/23/000070 Dutasteride Topical Solution 0.05% w/v(additional dosage form, Strength& indication)	M/s. Shilpa Medicare Limited	<p>In light of earlier SEC recommendations dated 17.11.2022, the firm presented Phase-III clinical trial protocol (protocol No. HAIR/SMHS/2023-01, version: 2.0, dated 26.02.2024) before the committee.</p> <p>After detailed deliberation, the committee recommended for grant permission to conduct Phase-III clinical trial as per protocol presented by the firm subject to condition that the firm should include more number of clinical trial sites which are equal numbers of Govt. & private sites and geographical distributed sites.</p>
8.	SND/IMP/23/000093 Crisaborole Ointment 2%w/w	M/s. Pfizer limited	<p>The firm presented the proposal for updation of dosage and administration section (Frequency of application) in package insert before the committee.</p> <p>The committee noted that such package insert is already approved by US FDA and other countries.</p> <p>After detailed deliberation, the committee recommended for proposed updation in dosage and administration section in the package insert.</p>
9.	SND/MA/24/000026 Roflumilast Cream 0.3% w/w (additional strength & indication)	M/s. Glenmark Limited	<p>The firm presented the proposal for grant of permission to manufacture and marketing of Roflumilast cream 0.3%w/w(additional strength & indication) along with justification and comparative in-vitro bioequivalence data</p>

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			<p>between Glenmark's test product & reference product (ZRYVE Cream) and requested for waiver of Phase-III clinical trial & Bio-equivalence study before the committee.</p> <p>The firm informed that the proposed formulation Roflumilast topical cream 0.3%w/w already approved in USA on 29.06.2022 and Canada on 27.04.2023 for same indication.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct bridging clinical trial to prove the efficacy and safety of the proposed formulation on the Indian population.</p> <p>Accordingly, the firm should submit Phase-III clinical trial protocol to CDSCO for further review by the committee.</p>