

Recommendations of the SEC (Dermatology & Allergy) made in its 08th/26 meeting held on 11.03.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/158/25 Online Submission (52810) C1 esterase inhibitor (plasma-derived, human)	M/s Premier Research Group (India) Private Limited	The firm presented phase III clinical trial protocol no. CONE-02-version 5.0 dated 11 December 2023. After detailed deliberation, the committee recommended for grant of permission to grant of permission to conduct the trial as presented by the firm with following condition. 1) Geographically distributed government site shall be included in the study. 2) PI/Co-PI could be mix of Dermatologists/ Paediatrician/ Immunologists. 3) IDMC interim analysis report of preliminary safety and efficacy for the adult patient to be submitted to CDSCO for review before initiating the study in the Paediatric population.
2.	CT/16/26 Online Submission (54633) Barzolvolimab CDX-0159	M/s PPD Pharmaceutical Development India Private Limited	The firm presented phase IIIb clinical trial protocol no. CDX0159-17 version 1.0 dated 03- July -2025. After detailed deliberation, the committee recommended for grant of permission to grant of permission to conduct the trial.
Medical Device Division			
3.	IMP/MD/2025/17289 6 Spincare Portable Wound Care System	M/s Vasu Organics Private Limited	The firm presented the proposal for grant of permission to import investigational medical device viz. Spincare Portable Wound Care System, manufactured by M/s Nanomedic Technologies LTD, Israel.

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			<p>The proposed product is marketed in UK and EU countries for more than two years.</p> <p>After detailed deliberation, the experts opined that the firm shall submit the following data for further deliberation:</p> <ol style="list-style-type: none"> 1) Clinical study data detailing stability, efficacy and safety generated on the said device in tropical climate countries. 2) List of tropical climate countries where the said device is approved for marketing, copy of regulatory approval along with the Post Marketing Surveillance data to be submitted.
Biological Division			
4.	E-115568 Rituximab Injection (RituxiRel™)	M/s. Reliance Life Sciences Private Limited	<p>The firm presented the PMS study report titled as “A Prospective Multi-centre, Non-interventional, observational Post marketing surveillance (PMS) study of RituxiRel™ (Rituximab) to evaluate long-term safety in patients with Pemphigus vulgaris in routine clinical practice.” vide Protocol No. RLS/PMS/2019/01; Version 1.0, dated: 15 Apr 2019.</p> <p>The committee noted the results of aforesaid PMS study and recommended updating of the Monitoring guidelines and adverse effects in the product insert (based on Indian data). The same may be submitted to CDSCO.</p>
5.	BIO/CT18/FF/2025/5 3250 Guselkumab solution for injection (r-DNA Origin) in single-use	M/s Johnson & Johnson Pvt. Ltd	The firm presented the proposal to for grant of approval of following additional indications of the drug product Guselkumab solution for injection (r-DNA Origin) in single-use pre-filled

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	Pre-Filled Syringe & single-use pre-filled pen 100 mg/ml for subcutaneous administration		<p>syringe & single-use pre-filled pen 100 mg/ml for subcutaneous administration along with a request for a local clinical trial waiver:</p> <ul style="list-style-type: none"> • Treatment of plaque psoriasis • Treatment of scalp psoriasis, nail psoriasis, and hand and foot psoriasis. • Improvement of health-related quality of life in adult patients with moderate to severe psoriasis who are candidates for phototherapy or systemic therapy. <p>The committee noted that the proposed indications are approved in 50 countries including USA, UK, Japan, Australia, Canada and EU.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed additional indications with the condition to conduct phase IV study in India.</p> <p>Accordingly, the firm shall submit the Phase IV protocol to CDSCO within 03 months of the grant of permission for additional indications.</p>
SND Division			
6.	SND/MA/25/000266 Diperoxochloric Acid Topical Solution 0.29 mg/ml	M/s Centaur Pharmaceuticals Pvt. Ltd	<p>The firm presented the proposal for grant of permission to manufacture and market Diperoxochloric Acid Topical Solution 0.29 mg/ml for addition indication i.e. for the treatment of arterial leg ulcers and mixed arterial venous leg ulcers along with Phase III CT study protocol before the committee.</p> <p>Firm presented that, Diperoxochloric Acid Topical Solution 0.29 mg/ml was</p>

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			<p>approved in India on 20.11.2019 for wound healing in diabetic neuropathic ulcers of skin and subcutaneous tissues reduction.</p> <p>After detailed deliberation, the committee recommended to conduct dose finding study before proceeding to Phase III Clinical study for proposed addition indication.</p> <p>Accordingly, the firm shall submit protocol for dose finding study for further evaluation by the committee.</p>
7.	<p>SND/MA/25/000218</p> <p>Cidofovir Topical Gel 1 % w/w and Cidofovir Topical Gel 3 % w/w</p>	M/s Emcure Pharmaceuticals Limited	<p>In light of the earlier SEC recommendation firm presented the revised Phase-III Clinical trial protocol before the committee.</p> <p>After detailed deliberation the Committee recommended to conduct study with two test arms, arm 1 (Cidofovir Topical Gel 1% w/w), arm 2(Cidofovir Topical Gel 3% w/w) and arm 3 (Standard of care). Further, committee recommended removing the placebo arm from the study.</p> <p>Accordingly, the firm should submit revised Clinical trial Protocol to CDSCO.</p>