

Recommendations of the SEC (Dermatology & Allergy) made in its 07th/24 meeting held on 11.07.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/84/23 Online Submission (33341) Spesolimab	M/s. IQVIA RDS	The firm presented clinical trial Phase IIIb/IV protocol amendment version 2.0 dated 23.01.2024 (protocol No. 1368-0120). After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/141/23 Online Submission (33342) SAR445229 / Amlitelimab	M/s. Sanofi	The firm presented clinical trial Phase III protocol amendment 01 version 01 dated 20.11.2023 (protocol No. EFC17559). After detailed deliberation, the committee opined that the data of clinical study conducted in adults shall be submitted to CDSCO for further review by committee before enrolment of adolescents and subjects less than 40kg weight.
3.	CT/12/24 Online Submission (41581) Rifamycin 1% Topical Solution	M/s. SpinoS Lifescience And Research Private Limited	In light of earlier SEC recommendation dated 07.02.2024, the firm presented Phase III clinical trial protocol No. SLS-CT-0005-23-RIFA version 02 dated 26.02.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.
Medical Devices Division			
4.	IMP/MD/2023/10476 6 Oxygen Delivery System (ODS) (Model No. : NA055- 30), Oxygen Delivery System (ODS) (Model No. :NA055- 01)	M/s.GR Health Aids Private Limited	The firm presented the proposal for grant of permission to import the medical devices NATROX Oxygen Wound Therapy System viz. 1. Oxygen Delivery System (ODS) and 2. NATROX® Oxygen Generator Kit (OG) manufactured by M/s Inotec AMD Ltd, United Kingdom.
5.	IMP/MD/2023/10474 0 NATROX® Oxygen Generator Kit (OG)	M/s. GR Health Aids Private Limited	The firm presented the summary of clinical trial data generated and published data supporting the clinical safety, performance & effectiveness of the above

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	(Model No.:NA040)		<p>said devices. The products are approved by the regulatory authorities of USA, UK, Australia and other countries. The said devices are marketed for more than two years in USA.</p> <p>After detailed deliberation, the committee recommended for consideration of the proposal with condition that firm shall conduct Post Marketing Clinical Investigation to generate the safety and effectiveness data in Indian population. Accordingly, the firm shall submit clinical investigation plan for conduct of such study within period of six months from launch of the product in the Indian market for further necessary action in the matter.</p>
New Drugs Division			
6.	12-1/24-DC(Pt-101) Trifarotene (AKLIEF®) 50 microgram/g cream	M/s Galderma India Pvt. Ltd.	<p>The firm presented the proposal for updating prescribing information of Trifarotene (AKLIEF®) 50 microgram/g cream based on CCDS version 4 dated 11th January 2024.</p> <p>After detailed deliberation, the committee recommended for the approval of updating prescribing information.</p>
7.	12-1/24-DC(Pt-58) Concentrate of Proteolytic enzyme enriched in Bromelain Topical Gel	M/s. Saara Medical Solution Pvt. Ltd.	The firm did not turn up for presentation.