

Recommendations of the SEC (Ophthalmology) made in its 69th meeting held on 22.08.2023 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMA/21/000043 Lifitegrast Ophthalmic Solution 5% w/v	M/s Ajanta Pharma Ltd.	The firm didn't turn up for presentation.
GCT Division			
2.	CT/180/22 Online Submission (26580) Faricimab	M/s Roche	<p>The firm presented their proposal for protocol no. ML43435, version 2 dated 16 August 2022 to waive off CTNOC condition No. 1 which stated that "The study drug IVT injection should only be administered to the trial subjects when subject's post prandial blood sugar level is less than 200mg/dl.</p> <p>After detailed deliberation, the committee recommended for waiver of the Condition No. 1 of the CT NOC as proposed. (Dr. Somesh Agrawal did not participate in deliberation.)</p>
3.	CT/34/22 Online Submission(26615) Afibercept	M/s Lupin	<p>The firm presented their proposal for protocol no, LRP/LUBT017/2021/003 version 1.0, dated 14 March 2022 to enroll additional 298 patients from India</p> <p>After detailed deliberation, the committee recommended that the firm should submit interim analysis results of the study in Russia & India before the committee for further review.</p>
Medical Device Division			
4.	CI/MD/2023/87103 Hyper CL™ Therapeutic Soft Contact Lens	M/s Nextvel Consulting LLP	<p>The firm presented their proposal for conduct of the Clinical investigation plan on the device Hyper-CL before the committee. The firm clarified that the proposed study is an Investigator specific study to be carried out by Dr. Agarwals Hospital , Tirunelveli, Tamil Nadu.</p> <p>The committee opined that the product is already approved in US FDA, Isreal and EU & also used in the Indian population before licensing regime. The committee after deliberation recommended that the proposed Clinical Investigation protocol no AEH-HCL-BK-01, Version 1.0 date 13.04.2023 for said device may be approved with the condition that the Clinical data generated in the study should not be used for the regulatory approval for the said device in the country.</p>