

Recommendations of the SEC (Ophthalmology) made in its 64th meeting held on 23.03.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2022/35068 Bevacizumab 25mg/ml	M/s. Reliance Life Sciences Pvt. Ltd.	In continuation of earlier SEC meeting dated 01.09.2022, the firm presented the proposal to conduct Phase I clinical trial titled "A prospective, multi-center, open label, single-arm, phase I clinical study to evaluate safety of R- TPR-023 in patients with neovascular (wet) age-related macular degeneration" vide protocol No.: RLS/OPT/2022/05, version 1.0, Date: 22-Nov-2022. After detailed deliberation, the committee recommended the approval of study protocol subject to the following. <ol style="list-style-type: none"> 1. The sample size should be increased to 16 subjects to achieve 12 evaluable subjects. 2. Treatment of other eye as per standard of care at the discretion of the PI should be included in the protocol. <p>Accordingly, the firm should submit revised protocol to CDSCO.</p>
3.	4-15/Bayer/PAC-R-Aflibercept/2023-BD Aflibercept Solution for intravitreal Injection 40mg/ml	M/s. Bayer Pharmaceuticals	The firm presented its proposal for updating the package insert along with justification. After detailed deliberation, the committee recommended for approval of changes made in package insert.
SND Division			
4.	12-44/2023-DC (Pt-Misc-SND) Moxifloxacin Ophthalmic Solution 0.5 % w/v	M/s. Novartis Healthcare Pvt. Ltd	The firm presented PMS study protocol (Protocol No. CUKG489C1IN01, Version: 00, Dated 02.03.2022) of Moxifloxacin Ophthalmic Solution 0.5 % w/v in perioperative (preoperative and postoperative) sterilization in patients undergoing Ophthalmic Surgery. After detailed deliberation, the committee recommended for grant of permission to conduct the PMS study as per the protocol presented by the firm.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
5.	FDC/MA/20/000095 Timolol + Brinzolamide + Brimonidine (5mg/ml + 10mg/ml +2mg/ml) eye drops	M/s. Micro Labs Ltd.	In light of earlier SEC recommendation dated 05.11.2020, the firm presented Phase III CT report. After detailed deliberation, the committee considered the Phase III CT report and recommended for grant of permission to manufacture and market the FDC with condition to conduct the Active PMS study. The active PMS study protocol should be submitted to CDSCO for review by the committee within 03 months.
6.	FDC/MA/23/000027 Moxifloxacin 0.1% w/v + Nepafenac 0.1% w/v ophthalmic solution	M/s. Akums	In light of earlier SEC recommendation dated 17.04.2015, the firm presented the revised Phase III CT protocol and ocular toxicity study data. After detailed deliberation, the committee recommended for conducting the Phase III clinical trial study. The result of the study should be presented before the committee.
GCT Division			
7.	CT/180/22 Online Submission (35358) Faricimab (R06867461)	M/s. Roche	The firm presented the proposed Phase IIIb ELEVATUM trial protocol no. ML43435, version 2.0 dated 16-Aug-2022 (India) before the committee. After detailed deliberation, the committee recommended the grant of permission to conduct the proposed trial with condition 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.