

Recommendations of the SEC (Ophthalmology) made in its 11th meeting held on 21.11.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	E-receipt-30114 Faricimab 6mg/0.05mL (120mg/mL) solution for intravitreal injection (Vabysmo®)	M/s. Roche Products (India) Private Limited	The firm presented the proposal for update in package insert for drug product Faricimab 6mg/0.05mL (120mg/mL) solution for intravitreal injection with respect to proposed changes in Sections of Postmarketing experience and clinical/efficacy studies. After detailed deliberation, the committee recommended for the approval of update in package insert Version 2.0 dated April 2024 for the proposed changes.
2.	BIO/CT04/FF/2024/4 4897 Aflibercept Solution for Injection 40 mg/ml in Vial	Ms. Intas Pharmaceuticals Ltd	The firm presented the proposal for the conduct of Phase III clinical trial titled “A Phase-3, Double-Masked, Two-Arm, Multiple Dose, Parallel Group, Randomized, Multicentre, Active-Controlled, Comparative Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of Aflibercept Intravitreal Injection and Eylea (Aflibercept) Intravitreal Injection in Patients with Diabetic Macular Oedema (DME)” vide Protocol 0252-24 Version: 1.0 dated 11.07.2024. After detailed deliberation, the committee recommended the firm to conduct the Phase III study as per presented protocol with the following conditions- 1. The acceptable fasting blood sugar and post prandial blood sugar levels should be clearly defined in the inclusion criteria. 2. Number of evaluable subjects in the test arm should be atleast 100. 3. Subjects should be discontinued from the study when there is any worsening condition/adverse event in the treatment eye. Subsequently, the patients should be provided with standard of care. 4. Treatment of other eye as per standard of care should be included in the protocol. Accordingly, revised protocol should be submitted to CDSCO for evaluation.

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Medical Devices Division			
3.	CI/MD/2024/114688 Femtosecond Ophthalmic solid-state laser system (Brand Name: WaveLight UV--Femtosecond Laser System, Model 1026 (UV fs-Laser) with accompanying WaveLight Disposable-Set UV fs-Laser Patient Interface, Model no.1507)	M/s. Alcon Laboratories (India) Pvt. Ltd.	<p>The firm re-deliberated the proposal for grant of permission for conduct of clinical investigation on applied device Femtosecond Ophthalmic solid-state laser system in the country on Indian population before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of clinical investigation in the country on Indian population. Hence, firm should submit report of the clinical investigation to CDSCO after its completion for review and further necessary action in the matter.</p>
New Drugs Division			
4.	ND/IMP/19/000107 0.6 % w/v Lubricant eye drops Propylene Glycol	M/s Alcon Laboratories (India) Private Limited	<p>In light of earlier SEC recommendation dated 22.09.2022 for fulfillment of condition no. 11 of Import & marketing permission granted to the firm in Form CT-20 dated 30.06.2020, the M/s Alcon Laboratories (India) Private Limited, presented Post Marketing Surveillance (PMS) report for 0.6 % w/v Lubricant eye drops Propylene Glycol, before the committee.</p> <p>After detailed deliberation, the committee noted and agreed to the result of the PMS report.</p>