Recommendations of the SEC (Ophthalmology) made in its 07th/25_meeting held on 16.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/73/25 Online Submission (49956) Aflibercept Solution for Injection 40 mg/ mL in Vial	M/s INTAS PHARMACEUTICALS LTD	The firm presented phase III clinical study Protocol No.: 0262-24 Version No. 3.0 dated 03-MAY-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. In the Inclusion criteria, the blood sugar levels (FBS, PPBS) should also be discretely defined, along with the HbA1C Level. 2. The Instruments to be used for intra ocular pressure (IOP) measurement should be specified in the protocol instead of allowing site preferred method. Dr. Somesh Aggarwal didn't participate.
Biological Division			
2.	BIO/CT18/FF/2024/45055 Faricimab 6 mg/ 0.05 ml solution for Intravitreal injection	M/s Roche Products (India) Private Limited	In light of the earlier SEC recommendations dated 19.12.2024, the proposal of firm for the approval of additional indication of Macular edema secondary to retinal vein occlusion (RVO) for the drug product- Faricimab 6 mg/0.05 ml solution for Intravitreal injection (VABYSMO®) was redeliberated with the justification of unmet need in India and long term safety data of drug in proposed indication from the Global clinical trial along with request of local Phase III clinical trial waiver with a commitment to conduct Phase IV study in the proposed indication. The committee noted that there is no appropriate & adequate long term safety data of drug product available in Indian

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			population. Further, Phase IV clinical trial in the already approved indication of nAMD and DME has not yet been conducted by the firm. After detailed deliberation the committee reiterated the earlier SEC recommendation dated 19.12.2024 and recommended the firm to conduct Phase III clinical trial for the proposed indication.
3.	BIO/CT18/FF/2025/49091 Faricimab 6 mg/ 0.05 ml solution for Intravitreal injection (VABYSMO); 120 mg/mL	M/s Roche Products (India) Private Limited	The firm presented the proposal for the change in recommended posology of the drug product Faricimab 6 mg/0.05 ml solution for Intravitreal injection (VABYSMO); 120 mg/mL from 4 loading doses to 3 loading doses for the approved indications of nAMD and DME based on the post-hoc efficacy analysis of Phase III interventional studies. The committee noted that the proposed change in posology is approved by EMA and MHRA. After detailed deliberation, the committee recommended for the proposed change in the posology of the approved drug product for the indications of nAMD and DME.
New Drugs Division			
4.	ND/CT/25/000046 FDC of Ranpirnase 0.3000 mg/ml + Oxymetazoline Hydrochloride1.0 mg/ml U.S.P.+ Tobramycin 3.0000 mg/ml U.S.P. Eye Drop	M/s CBCC Global Research LLP	Firm presented a proposal for grant of permission to conduct the Phase-II Clinical Trial Study of drug OKG-0303 (FDC of Ranpirnase 0.3000 mg/ml + Oxymetazoline Hydrochloride 1.0 mg/ml U.S.P. + Tobramycin 3.0000 mg/ml U.S.P. Eye Drop) vide protocol No. (OKG-0310, Version No. 2.0, dated 27/June/2025), before the committed. The committee has noted following: • That the drug Tobramycin & Oxymetazoline Hydrochloride has not been approved for the

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			proposed indication. • Drug Tobramycin & Oxymetazoline Hydrochloride has not been approved anywhere as FDC. • Combination of Ranpirnase + Tobramycin + Oxymetazoline has not been approved anywhere and more over it has not been tested for potential proposed therapeutic indication. After detailed deliberation, the committee recommended that firm should submit data/ preclinical study showing: - Potential therapeutic benefits for proposed indication. - Adequate justification/ rational for the combination of the product. - Firm may come up with Phase-I CT protocol or justification for waiver of Phase-I CT.
FDC Division			
5.	FDC/CT/25/000024 Phenylephrine 1% + Ketorolac 0.3% intraocular solution	M/s COD Research Pvt. Ltd.	The firm presented the proposal along with Phase III CT protocol before the committee. After detailed deliberation, the committee opined that: 1. The firm should include the SOP regarding how the formulation will be dispensed in the Operation Theatre. 2. Pre-operative dilation should be standardized across all patients. 3. Outcome should be the change in the pupillary diameter size. 4. The firm should include the SOP for videography of measurement of pupillary diameter size. 5. The instrument by which intra-ocular pressure will be measured should be specified. 6. Cycloplegic and tear substitute should be mentioned in the list of prohibited medication.

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			Accordingly, the firm should submit revised Phase III clinical trial protocol to CDSCO for further review by the committee.