Recommendations of the SEC (Oncology) made in its 12th/26 meeting held on 22.04.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/40/26 Online Submission (55559) Ramantamig (JNJ-79635322)	M/s. Johnson & Johnson Pvt. Ltd.	The firm presented phase III clinical study protocol no. 79635322MMY3002 Amendment 1 dated 19 February 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/44/26 Online Submission (55602) BMS-986545 / PUMITAMIG	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented phase III clinical study protocol no CA2660001, Original Protocol dated 09-Dec-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
3.	BIO/CT21/BO/2025/50981 Bevacizumab DP 25 mg/mL concentrate for solution for infusion (100 mg/4 mL & 400 mg/16 mL vial) (Drug Product)	M/s. CuraTeQ Biologics Private Limited	The firm presented the proposal for grant of permission to manufacture and market Bevacizumab concentrate for solution for infusion 25 mg/mL (100 mg/4 mL & 400 mg/16 mL vial) (r-DNA origin) based upon the results of comparative Phase 1 & Phase 3 clinical trial conducted in India on metastatic colorectal cancer patients. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Bevacizumab concentrate for solution for infusion 25 mg/mL (100 mg/4 mL & 400 mg/16 mL vial) (r-DNA origin) for the treatment of patients with Metastatic Colorectal Cancer, subject to the condition that firm shall conduct Phase IV study in India. Accordingly, firm shall submit Phase IV Clinical Trial protocol to CDSCO within 03 months of grant of marketing

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			authorization permission. Note: - Dr. Kaushal Kalra did not participate in the SEC deliberation.
4.	BIO/CT04/FF/2025/51502 Pembrolizumab Solution for Infusion 100 mg /4 mL Vial (25 mg/mL).	M/s. Enzene Biosciences Ltd.	In light of earlier recommendation of SEC (Oncology) dated 23.12.2025, the firm presented revised protocol to conduct a Phase III clinical trial titled "A Phase III, multicenter, randomized, double blind, parallel group, comparative study to evaluate the efficacy, safety, pharmacokinetics and immunogenicity of proposed biosimilar Pembrolizumab versus KEYTRUDA® (Pembrolizumab) in combination with pemetrexed and platinum based chemotherapy in adult patients with Metastatic Non-Small Cell Lung Cancer" as per Protocol No.: ALK46/ENZ146-PEM1, Version No.: 2.0, dated 09 March 2026. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial as per the protocol presented by the firm.
5.	BIO/CT04/FF/2025/53488 Atezolizumab Injection 1875 mg/ 15mL	M/s. Roche Products (India) Private Limited	The firm presented the proposal for grant of permission to conduct Phase IV clinical trial titled as "A Phase IV, open-label, multicohort study to evaluate the safety and efficacy of subcutaneous Atezolizumab (Tecentriq SC) in Indian adult patients with Non-Small Cell Lung Cancer (NSCLC) vide protocol no. ML46561 Version 1.0 dated 09.12.2025. After detailed deliberation, the committee recommended the firm to recalculate the sample size based upon appropriate statistical assumptions and accordingly submit the revised protocol to CDSCO for further evaluation by the committee.