Recommendations of the SEC (Oncology)made in its 16th/26 meeting held on 18.06.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/76/26 Online Submission (56940) PF-08634404, 20mg/ml, Concentrate for solution for infusion	M/s. Pfizer Limited.	The firm presented phase III clinical study protocol no.: C6461003 Final Protocol Amendment 2 dated 16 October 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the all PI shall be Medical Oncologist only.
2.	CT/70/26 Online Submission (56765) HQP1351 (Olverembatinib)	M/s. IQVIA RDS (India) Private Limited.	The firm presented phase III clinical study protocol No. HQP1351AG301 Version no. 2.7 India dated 26 March 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that DSMB should be included in the trial protocol to oversee and ensure the safety of subjects and Interim safety reports should be submitted to CDSCO for review. Further, all PI shall be Medical Oncologist only.
3.	CT/69/26 Online Submission (56683) 1.Datopotamab D eruxtecan (DS-1062a) Powder for solution forinfusion100 mg/vial 2. Rilvegostomig (AZD2936) Concentrate for Solution for infusion, 750mg/vial (50mg/mL)	M/s. AstraZeneca Pharma India Limited.	The firm presented phase III clinical study protocol no. D763TC00001 version no. 1.0 dated 05 Feb 2026 CSP – Addendum India Version 1.0 dated 26-Feb-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
4.	BIO/CT04/FF/2026/55295 ASP200 (Pembrolizumab) Injection 100mg/4ml (25mg/ml) concentrate for solution for infusion	M/s. Kemwell Biopharma Private Limited.	The firm presented the proposal to conduct Phase 1/III clinical trial titled "A Randomized, Two Arm, Double-Blind, Parallel, Multicentre, Study to Compare Efficacy, Safety, Pharmacokinetics, and Immunogenicity of ASP200 (Pembrolizumab biosimilar) With Keytruda® in Adult Participants with Metastatic Non-Squamous Non-Small Cell

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			Lung Cancer (NSCLC)." as per Protocol No. CRD-083 Version 1.0 dated 24.02.2026. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I/III clinical trial as per the presented protocol, subject to the following conditions: 1. The firm shall constitute an independent Drug Safety Monitoring Board (DSMB) and submit periodic safety assessment reports to CDSCO. 2. All PIs shall be Medical Oncologist. 3. Day care facilities shall not be used as a clinical trial site 4. Clinical trial sites shall be geographically distributed 5. Post-trial access of the study drug shall be provided to the subjects until disease progression. Note: Dr. Kaushal Kalra has not participated in the deliberation.
5.	Receipt No. E-125472 Pertuzumab-Trastuzumab Injection 600 mg+600 mg [10 ml/15cc vial] and 1200 mg+600 mg vial [15 ml/20 cc vial] (Phesgo®)	M/s. Roche Products (India) Pvt. Ltd.	The firm presented the phase IV study report titled as "A Phase IV, Randomized, Multicenter, Open- Label, Crossover Study to Evaluate the Safety and Efficacy of Subcutaneous Administration of the Fixed-Dose Combination of Pertuzumab And Trastuzumab (Phesgo) in Indian Patients With HER2-Positive Breast Cancer" vide Protocol Number: ML44030, Version Number: 1.0, dated: 02-Feb-2022. The committee noted the results of aforesaid Phase IV study.
6.	BIO/CT04/FF/2025/53853 Amivantamab solution for injection 350 mg	M/s. Johnson & Johnson Pvt. Ltd.	The firm presented the proposal to conduct a Phase IV clinical trial titled "A Phase 4, Open-Label Study to Evaluate Safety of Amivantamab in Combination With Chemotherapy in Indian Patients With Locally Advanced or Metastatic Non-Small Cell Lung Cancer With EGFR Exon 19del or Exon21 L858R Mutations After Progression on Osimertinib", Version: Amendment 1 dated 29.04.2026" vide Protocol No. 61186372NSC4018; Phase 4, Version: Amendment 1, Date: 29 April 2026.

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			After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the protocol presented by the firm subject to the condition that All PIs shall be Medical Oncologist.
7.	(E-receipt No.: 113557) (Ramucirumab 10 mg/mL concentrate for solution for infusion)	M/s. Eli Lilly and Company (India) Pvt. Ltd.	The firm presented the proposal for update of Package Insert (PI) of Cyramza (Ramucirumab 10 mg/mL Concentrate for Solution for Infusion) Version dated 05.09.2025 with inclusion of paediatric data. After detailed deliberation, the committee noted that the supporting clinical data presented by the firm were generated on 30 patients only. The committee further observed that the submitted data lacked adequate relevance to the Indian clinical context and was not considered sufficient to justify the proposed update to the Package Insert. Accordingly, the committee did not recommend the proposed update to the Package Insert.
8.	BIO/CT04/FF/2026/54771 TPI-120 (Pegfilgrastim) pre-filled syringe 6mg with On-body injector	M/s. Kashiv Bio Sciences Private Limited.	The firm presented the proposal to conduct Phase I clinical trial titled "An open label, randomized, crossover, single dose study to compare pharmacokinetic, immunogenicity and safety of TPI-120 (Pegfilgrastim) pre-filled syringe 6mg with On-body injector and Fylnetra pre-filled syringe 6mg (Pegfilgrastim Injection 6mg/0.6ml PFS) in healthy adult human participants." as per Protocol No. TPI120-105, Ver. 1.0, dated December 30, 2025 for export purpose. After detailed deliberation, the committee did not consider the proposal of firm at this stage. The committee observed that the proposed study primarily involves comparison of a Pegfilgrastim prefilled syringe with an On-body Injector presentation against an approved prefilled syringe presentation and, therefore, entails evaluation of device-related aspects in addition to clinical considerations. Accordingly, the committee recommended that the proposal be deliberated again with

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			the involvement of subject experts from the medical devices domain to adequately assess the device-related components of the proposed study before further consideration.