Recommendations of the SEC (Oncology) made in its 07th/26 meeting held on 26.02.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/187/25 Online Submission (53864) Trastuzumab Rezetecan for Injection 100mg/vial	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented phase III clinical study protocol no. GSP 402-301 (SHR-A1811-315_Extension), version no. 3.0 dated 18 December 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. PI shall be Medical Oncologist only. 2. Day care center should not be a part of clinical trial. Dr. Kaushal Kalra didn't participate in the discussion.
2.	CT/05/26 Online Submission (54097) BMS 986504	M/s. Bristol-Myers Squibb India Pvt. Ltd	The firm presented phase II/III clinical study protocol no. CA2400029, amendment 01 dated 24 June 2025. After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee. 1. Scientific justification for the proposed sample size of 14 subjects in India, which constitutes less than 5% of the total global sample size of 590 subjects. 2. Demonstrate that the data generated from these 14 subjects will be sufficient to support marketing authorization in India upon successful completion of the clinical trial.
Biological Division			
3.	BIO/CT18/FF/2025/52447 Tislelizumab Injection100 mg (10ml)/Vial (r-DNA origin)	M/s. Glenmark Pharmaceuticals Ltd	The firm presented the proposal for grant of approval of following additional indications of the drug Tislelizumab Injection 100 mg (10ml)/Vial (r-DNA origin) along with a request for a local clinical trial waiver: 1. Tislelizumab in combination with platinum-based chemotherapy is indicated for the first-line treatment of patients with unresectable, locally advanced or metastatic esophageal squamous

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			cell carcinoma with a PD-L1 expression ≥ 1%. 2. Tislelizumab in combination with platinum and fluoropyrimidine-based chemotherapy, is indicated for the first-line treatment of adult patients with HER-2 negative locally advanced unresectable or metastatic gastric or gastro-esophageal junction (G/GEJ) adenocarcinoma with a PD-L1 expression ≥ 1%. 3. Tislelizumab in combination with etoposide and platinum-containing chemotherapy is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (SCLC). After detailed deliberation, the committee recommended that the firm shall submit data of on-going Phase IV study prior to consideration of the proposed additional indications. Accordingly, the firm shall submit safety data of Phase IV study for further evaluation by the committee.
4.	BIO/CT18/FF/2025/52443 Durvalumab Solution for Infusion 120 mg/2.4 ml and 500 mg/10 ml	M/s. AstraZeneca Pharma India Limited.	The firm presented the proposal for grant of approval of following additional indication of Durvalumab Solution for Infusion 120 mg/2.4 mL and 500 mg/10 mL (IMFINZI), aligned with the EU-approved indication: Durvalumab is indicated for the treatment of patients with unresectable hepatocellular carcinoma (uHCC) who have not received prior systemic therapy. The Committee noted that Durvalumab Solution for Infusion 120 mg/2.4 mL and 500 mg/10 mL (IMFINZI) has been approved in India since June 2018. The Committee further noted that the proposed indication is approved in 39 countries including the European Union, Japan and Canada. After detailed deliberation, the Committee recommended grant of approval for the proposed additional indication.

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5.	BIO/CT04/FF/2025/52329 Nivolumab Concentrate for solution for infusion, 100 mg/10 mL (10 mg/mL)	M/s. Shilpa Biologicals Private Limited.	In light of earlier recommendation of SEC (Oncology) dated 23.12.2025, the firm presented revised protocol to conduct a Phase I/III clinical trial titled "A Phase I/III, Randomized, Multicentre, Double-Blind, Two-Arm, Parallel-Group, Comparative Clinical Study to Investigate the Efficacy, Immunogenicity, Safety, and Pharmacokinetics of SBPL-Nivolumab Biosimilar Versus Reference Nivolumab in Study Participants with Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)" as per Protocol No. 25-AGCR-004, Version 4.0 dated 19.02.2026. After detailed deliberation, the committee noted that the proposed sample size is not adequate as per the inclusion criteria of the study-protocol. Therefore, the Committee recommended that the sample size shall be increased to align with the inclusion criteria. Accordingly, the revised protocol shall be submitted to CDSCO for further evaluation by the committee**.**
SND Division			
6.	SND/CT/25/000144 Apalutamide Tablets 60mg	M/s Hetero Labs Limited	Firm presented proposal for grant of permission to conduct Phase IV Clinical Trial protocol before the committee. After detailed deliberation, the committee recommended grant of permission to conduct Phase IV Clinical Trial as per the protocol presented by the firm with the following conditions- (i) Number of study participants should be at least 400 and patients shall be equally distributed for metastatic castration-resistant prostate cancer (M-CRPC) and non-metastatic, castration resistant prostate cancer (NM-CRP). (ii) Firm should include more number of clinical trial sites and at least 50% should be government sites and should be geographically distributed. (iii) Medical Oncologist shall be the Investigator for each clinical trial site.