Recommendations of the SEC (Oncology) made in its 14th/26 meeting held on 20.05.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2025/52544 Trastuzumab deruxtecan 100mg/5mL vial lyophilized powder for concentrate for solution for infusion	M/s. Astra Zeneca Pharma India Limited	The firm presented the proposal for grant of approval for the following additional indication of Trastuzumab deruxtecan 100 mg/5mL vial lyophilized powder for concentrate for solution for infusion. • Trastuzumab deruxtecan in combination with pertuzumab is indicated for the first-line treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+ or ISH+) breast cancer. The committee noted that the proposed indication is approved in US and firm has conducted global clinical study wherein India is one of the participating countries. After detailed deliberation, the committee recommended for grant of approval for the proposed additional indication with 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 authorization permission.
2.	BIO/CT04/FF/2026/54787 Daratumumab solution for intravenous infusion 100 mg/ 5ml and 400mg/20mL (20mg/ml)	M/s. Zydus Life Sciences Limited	The firm presented the proposal to conduct Phase III clinical trial titled "A Phase 3, Multicenter, Randomized, Double-Blind, Parallel-Group Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Immunogenicity of ZRC-3296 (Biosimilar Daratu-mumab) Compared with Reference Daratumumab (Darzalex®), each administered in Combination with Lenalidomide and Dexamethasone, in Patients with Newly Diagnosed Multiple Myeloma Ineligible or Deferred for Autologous Stem Cell Transplantation vide protocol no. DARA.25.001 dated 22.12.2025" After detailed deliberation, the

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			committee recommended for grant of permission to conduct Phase III clinical trial as per the protocol presented by the firm subject to the following conditions:- 1. The firm shall submit periodic DSMB review reports to CDSCO for close monitoring of adverse events and patient safety. 2. The proposed study shall be designated as Phase I/III clinical trial. 3. All PIs should be Medical Oncologist and Qualified Hematologist. 4. Day care facilities should not be used as a clinical trial site. 5. Clinical trial sites should be geographically distributed. 6. Number of patients shall be proportionate across all the clinical trial sites. 7. Post-trial access of the study drug shall be provided to the subjects till disease progression. The Committee further opined that, prior to grant of permission, CDSCO shall verify the proposed number of subjects in the clinical trial through a Biostatistician. Note: - Dr. Kaushal Kalra has not participated in the deliberation.
3.	BIO/CT04/FF/2026/54962 Pembrolizumab (MK-3475)	M/s. MSD Pharmaceuticals Private Limited.	The firm presented the proposal to conduct Phase 4 clinical trial titled "A Prospective, Open-label, Phase 4 Study to Evaluate the Safety of Pembrolizumab (KEYTRUDA®) in Combination with Indication-specific Chemotherapy or Chemo-radiotherapy in Participants Across Multiple Indications in India (KEYNOTE-G44) vide protocol no. MK-3475-G44-00 dated 08.01.2026. After detailed deliberation, the committee recommended grant of permission to conduct the Phase IV clinical trial as per the protocol presented by the firm subject to the following conditions:-

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			1. Clinical trial sites should be geographically distributed. 2. Number of patients shall be proportionate across all the clinical trial sites. Note: - Dr. Kaushal Kalra has not participated in the deliberation.
4.	BIO/CT04/FF/2026/54963 Nivolumab concentrate for solution for Infusion 10mg/ml (r-DNA Origin)	M/s. Zydus Life Sciences Limited	The firm presented the proposal to conduct Phase IV clinical trial titled "A Phase IV, Prospective, Multicenter, Open Label, Single-Arm Study to evaluate the Safety and Efficacy of Nivolumab for Selected Advanced Malignancies vide Protocol no: C2B06579, Version No.: 01 dated 03.02.2026. The Committee noted that the firm was granted permission to manufacture and market Nivolumab Concentrate Solution for Infusion (10 mg/mL) with the condition that the firm shall conduct a Phase IV study in the country for all approved indications, including locally advanced or metastatic non-small cell lung cancer. However, the firm has proposed the Phase IV study in the following three indications only: 1. Advanced or Metastatic Gastric Cancer, Gastroesophageal Junction (GEJ) Cancer and esophageal Adenocarcinoma. 2. Advanced Renal cell Carcinoma (RCC). 3. Recurrent or Metastatic Squamous Cell Carcinoma (SCC) of the Head and Neck. After detailed deliberation, the committee recommended grant of permission to conduct the Phase IV clinical trial as per the protocol presented by the firm. Further, the firm shall submit a separate application for conduct of the Phase IV study for the remaining approved indications with respect to Nivolumab Concentrate Solution for Infusion (10 mg/mL).

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5.	BIO/CT21/BO/2026/55261 Trastuzumab Emtansine Powder for Concentrate for Solution for Infusion 100 mg/Vial and 160 mg/Vial	M/s. Intas Pharmaceuticals Limited	The firm presented the proposal for grant of permission to manufacture and market the Drug Product Trastuzumab Emtansine Powder for Concentrate for Solution for Infusion 100 mg/Vial and 160 mg/Vial based on the results of Phase-III clinical trial conducted by the firm to establish the Efficacy, Safety, Immunogenicity and Pharmacokinetics of Proposed Trastuzumab Emtansine Biosimilar Compared with Kadcyla® in HER2-Positive Unresectable Locally Advanced or Metastatic Breast Cancer Patients Who Have Received Prior Treatment with Trastuzumab and a Taxane. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Trastuzumab Emtansine Powder for Concentrate for Solution for Infusion 100 mg/Vial and 160 mg/Vial for the following indications with the condition that firm shall conduct Phase IV study in India. 1) Metastatic Breast Cancer (MBC) - As a single agent for the treatment of patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who have received prior treatment with trastuzumab and a taxane. 2) Early Breast Cancer (EBC) - As a single agent for the adjuvant treatment of adult patients with HER2-positive early breast cancer who have residual disease, in the breast and/or lymph nodes, after pre-operative systemic treatment that included HER2 targeted therapy. Accordingly, firm shall submit Phase IV Clinical Trial protocol to CDSCO within 03 months of grant of marketing authorization permission.
6.	e-Receipt No.:145302 Pembrolizumab concentrate for solution for Infusion in	M/s. Hetero Biopharma Limited.	The firm presented the proposal of amendment in clinical trial protocol titled as “A Prospective, Randomized, Double Blind, Multiple Dose,

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	Vial 25mg/mL (100mg/4 mL) (rDNA origin)		Multicenter, Active Controlled, Comparative, Parallel Study to Evaluate the Efficacy, Safety, Pharmacokinetic and Immunogenicity of Intravenous Infusion of Hetero-Pembrolizumab (Hetero Biopharma Ltd, India) and Reference Medicinal Product (Pembrolizumab, Merck Sharp & Dohme B.V) in Patients with Non-Squamous Type of Metastatic Non-Small Cell Lung Carcinoma (mNSCLC) bearing no. HCR/III/PEMBNSCLC/06/2024, from Version 1.0. dated 16.08.2024 to Version 1.2 dated 09-Apr-2026 After the detailed deliberation, the committee recommended the amendment in protocol presented by the firm with Version 1.2 dated 09-Apr-2026.
New Drugs Division			
7.	ND/IMP/26/000004 Aumolertinib Tablets 55 mg	M/s. Glenmark Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 07.04.2026, the firm presented PK study data in Chinese and non-Chinese population along with Phase IV Clinical Trial Protocol. The committee noted that firm did not present subset analysis data of Phase III Clinical trial on South-east Asian population. Therefore, the committee recommended to conduct bridging-PK/PD study in target Indian population. Accordingly, firm should submit PK/PD study protocol to CDSCO for further review by the committee.
8.	ND/IMP/24/000077 Lazertinib Film Coated tablet 80 mg and 240 mg	M/s. Johnson & Johnson Pvt. Ltd.	In light of earlier SEC recommendation dated 11.02.2025 wherein firm presented global Phase-III Clinical Study report along with commitment for Phase IV CT protocol. The committee reviewed the complete global Phase III CT report including data generated from Indian subjects, as presented by the firm. Further, the committee noted that the drug is approved in the United States,

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			European Union, United Kingdom, and Canada etc. After detailed deliberation, the committee recommended for the grant of permission for the import and marketing of the drug, Lazertinib Film Coated tablet 80 mg and 240 mg for proposed indication with waiver of local Phase III clinical trial subject to the condition that: • The firm should conduct Phase IV clinical trial for which the protocol should be submitted with appropriate number of subjects within 3 months of approval of the drug for review by the committee. • The drug should be sold by retail on the prescription of a medical oncologist only.