Recommendations of the SEC (Oncology) made in its 18th/26 meeting held on 08.07.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/54/26 Online Submission (56031) Epetraborole Tablets, 250 mg	M/s. CBCC Global Research LLP	The firm presented phase II clinical study protocol no. EBO-PV-201 version no. 1.0 dated 02-APR-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1) Ruxolitinib should be allowed as a rescue medicine along with Phlebotomy. 2) The duration of persistence shall be better designed for the clarification of Investigators on persistence of haematocrit > 50%.
2.	CT/77/26 Online Submission (57069) KNX517 (atezolizumab)	M/s. Syneos Health India Private Limited	The firm presented phase III clinical study protocol no. CKNX517A12101version number: 1.0 dated 13-May-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. The protocol shall be revised to increase the duration of study for one year or the post-trial access shall be provided to the patients considering the duration of treatment. 2. EGFR/ALK shall be negative for all the subjects included in the study.
3.	CT/83/26 Online Submission (57367) Mocertatug rezetecan (GSK5733584)	M/s. GSK Pharma India Private Limited	The firm presented phase III clinical trial protocol no. 224031, protocol amendment 1 Final dated 09-APR-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/86/26 Online Submission (57505) Elritercept (TAK-226)	M/s. IQVIA RDS (India) Private Limited	The firm presented phase III clinical trial protocol no. TAK-226-3002 original dated 27 March 2026. After detailed deliberation, the committee recommended for grant of permission to

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			conduct the trial as presented by the firm with condition that government and private sites should be considered proportionately as advised.
Biological Division			
5.	BIO/CT18/FF/2025/52530 Trastuzumab Deruxtecan Powder for Concentrate for Solution for Infusion 100 mg (ENHERTU)	M/s. AstraZeneca Pharma India Limited	The Firm presented the proposal for the grant of approval of the following additional indication of the already approved drug product, Trastuzumab Deruxtecan Powder for Concentrate for Solution for Infusion 100 mg (ENHERTU). "ENHERTU followed by a taxane, trastuzumab, and pertuzumab (THP) is indicated for the neoadjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) Stage II or III breast cancer". The committee noted that the subject drug product is approved in India since May 2023. The committee further noted that proposed additional indication is approved in the US, based on the global Phase-III (Destiny-Breast 11) study data where India is the participating country. After detailed deliberation, the committee recommended the grant of approval for the proposed additional indication, in line with the USFDA.
6.	BIO/CT04/FF/2025/50397 Sintilimab Injection 100 mg/10 ml (per vial) (Intravenous Infusion)	M/s. Mankind Pharma Ltd.	The firm presented a proposal to conduct a clinical trial titled, "A Phase I, Open-Label, Single-arm study to evaluate Safety, Tolerability, Pharmacokinetics, and Immunogenicity of Sintilimab plus Chemotherapy in Patients with Locally Advanced or Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC) vide protocol no. MPL-SIN-002 version 1.0 dated 08.04.2026. After detailed deliberation, the committee recommended the following changes in the study protocol: 1. The inclusion criteria shall be updated to include patients with later line of

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			treatment with advanced metastatic NSCLC (Stage IV or onwards). 2. The safety assessment of the study drug shall be designed in patients receiving the study drug as monotherapy. 3. Clinical trial sites shall be geographically distributed Accordingly, the firm shall submit the revised protocol to the CDSCO for further evaluation by the committee.
7.	BIO/CT18/FF/2026/54521 Trastuzumab Deruxtecan Powder for Concentrate for Solution for Infusion 100 mg (ENHERTU)	M/s. AstraZeneca Pharma India Ltd	The Firm presented the proposal for the grant of approval of the following additional indication of the already approved drug product, Trastuzumab Deruxtecan Powder for Concentrate for Solution for Infusion 100 mg (ENHERTU). "ENHERTU is indicated for the adjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) breast cancer who have residual invasive disease following neoadjuvant Trastuzumab (with or without Pertuzumab) and taxane-based treatment." The committee noted that the subject drug product is approved in India since May 2023. The committee noted that the proposed indication is approved in the US, based on the global Phase-III (Destiny-Breast 05) study data. After detailed deliberation, the committee considered the local Phase-III clinical trial waiver and recommended the grant of approval for the proposed additional indication, considering the significant therapeutic advancement over the current standard of care, in line with the USFDA; subject to the condition that firm shall conduct the Phase-IV clinical trial in India. Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission.

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8.	BIO/CT21/FF/2025/47302 Nivolumab injection (r-DNA origin) 40 mg/4 mL and 100 mg/ 10 mL (10 mg/mL)	M/s. Zydus Lifesciences Limited	The Firm presented the following additional indications of the drug product Nivolumab Injection 40 mg/4 mL and 100 mg/10 mL (10 mg/mL) by the way of extrapolation in line with the indication approved for the innovator product based on prescribing information. 1. Malignant Pleural Mesothelioma (MPM): Nivolumab, in combination with ipilimumab, for the first-line treatment of adult patients with unresectable malignant pleural mesothelioma. 2. Hepatocellular Carcinoma (HCC): Nivolumab, in combination with ipilimumab, for the treatment of adult patients with hepatocellular carcinoma who have received prior treatment with sorafenib. The committee noted that the subject drug product of M/s Zydus Lifesciences Ltd. is approved in India vide permission no. MF/BIO/24/000136 dated 27.12.2024 with the condition that the firm shall conduct a Phase IV clinical study in the country for all approved indications, including locally advanced or metastatic non-small cell lung cancer. After detailed deliberation, the committee recommended to submit the compliance status of the Phase IV condition as mentioned under the permission no. MF/BIO/24/000136 dated 27.12.2024. Accordingly, the firm shall submit the respective compliance status of Phase-IV condition of all approved indications for further evaluation by the committee.