Recommendations of the SEC (Oncology) made in its 10th/26 meeting held on 23.03.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2025/ 53742 Atezolizumab Injection 1200 mg/20 ml Vial	M/s. Roche Products (India) Private Limited	The firm presented the proposal to conduct Phase IV clinical trial titled "A Phase IV, open-label, multicenter study to evaluate the safety and efficacy of intravenous Atezolizumab (tecentriq®) as first-line treatment in Indian adult patients with advanced or metastatic non-small cell lung cancer (NSCLC) who are ineligible for platinum based therapy" as per Protocol No. ML46695 Version 1.0 dated 11 Dec 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the presented protocol, subject to the following conditions: 1) All PIs shall be Medical Oncologist. 2) Day care facilities shall not be used as a clinical trial site. 3) Clinical trial sites shall be geographically distributed. 4) Number of patients shall be proportionate between government and private clinical trial sites. 5) Post-trial access of the study drug shall be provided to the subjects until disease progression.
2.	BIO/CT04/FF/2025/ 53788 Elranatamab 40mg/mL (Elduxio) Solution for Injection (Subcutaneous)	M/s. Pfizer Products India Private Limited	The firm presented the proposal to conduct Phase IV clinical trial titled “A phase-4 Multicenter, Open-Label, Single-Arm Study Evaluating Elranatamab as Monotherapy in Adult Patients with Relapsed/Refractory Multiple Myeloma in India, with at least four prior therapies, including an immunomodulatory agent, a Proteasome inhibitor and an anti-CD38 antibody” as per Protocol No. C1071053 dated 18-Dec-2025 After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial subject to the following conditions: 1) Sample size shall be increased to at

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			least 100 subjects. 2) All PIs shall be Medical Oncologist or Hematologist. 3) Day care facilities shall not be used as a clinical trial site. 4) Clinical trial sites shall be geographically distributed. 5) Number of patients shall be proportionate between government and private clinical trial sites. 6) Post-trial access of the study drug shall be provided to the subjects until disease progression. Accordingly revised protocol shall be submitted to CDSCO for further evaluation.
3.	BIO/CT21/FF/2025/ 53838 Trastuzumab 150 mg lyophilized powder in Single Dose Vial and Trastuzumab 420 mg lyophilized powder in Single Dose Vial	M/s. CuraTeQ Biologics Private Limited	The firm presented the proposal for approval of additional indication of already approved biosimilar Trastuzumab by the way of extrapolation for the treatment of HER2 positive early breast cancer and metastatic gastric cancer. The committee noted that the subject drug product of the firm is approved since 27 March 2024 and proposed indications are already approved for innovator drug product. After detailed deliberation, the committee recommended for approval of additional indications by the way of extrapolation with a condition to conduct Phase IV study in the proposed indications. Accordingly, the protocol to conduct the Phase IV study shall be submitted to CDSCO within three months of grant of permission for the proposed additional indications.
4.	BIO/CT21/FF/2025/ 53876 Pertuzumab injection (rDNA origin) 420mg/ 14 mL	M/s. Enzene Biosciences Ltd.	The firm presented the proposal for approval of additional indication of already approved biosimilar Pertuzumab injection (rDNA origin) 420 mg/14 mL by the way of extrapolation for Early breast cancer i.e., "Biosimilar Pertuzumab is indicated for use in combination with Trastuzumab and chemotherapy in: • The neoadjuvant treatment of adult

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			patients with HER2-positive, locally advanced, inflammatory or early stage breast cancer at high risk of recurrence. • The adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence". The committee noted that the subject drug product of the firm is approved since 13 June 2024 and proposed indication is already approved for innovator drug product. After detailed deliberation, the committee recommended for approval of additional indication by the way of extrapolation with a condition to conduct Phase IV study in the proposed indication. Accordingly, the protocol to conduct the Phase IV study shall be submitted to CDSCO within three months of grant of permission for the proposed additional indication.
New Drug Division			
5.	ND/38/2026-eoffice Alpelisib Film coated tablets 50 mg ,150 mg and 200 mg	M/s. Novartis Healthcare Private Limited Ltd.	The firm did not attend the meeting.
6.	ND/CT/25/000017 (ND/25/2026-eoffice) Pyrotinib Maleate Tablets 80 mg	M/s. Dr. Reddy's Laboratories Ltd	The firm presented amendment to Phase-III clinical trial protocol of Pyrotinib Maleate Tablets 80 mg (Protocol ID.: DRL-IND-NDA14-PYR-CAP/2023; Version 2.1; dated: 16-DEC-2025), before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial with Pyrotinib Maleate Tablets 80 mg as per the amended protocol presented by the firm. The results of Phase III Clinical Trial should be submitted to CDSCO for further review by the committee.
7.	ND/112/2025-eoffice Tepotinib Film Coated	M/s. Merck Specialities Private Limited	The firm did not attend the meeting.

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	Tablets 250 mg (TEPMETKO)		
8.	ND/55/2026-eoffice Oseltamivir	SCRP , Disaster Management Cell under the Ministry of Health & Family Welfare	The study investigator presented protocol titled "A Phase II open-label clinical trial for Oseltamivir In Platinum Refractory Ovarian cancer: Mathematical Modelling Integration for Systemic therapy (PROMMIS)" with BIORRAP ID: ALL50102025" before the committee. After detailed deliberation, the committee recommended that applicant should submit the following: 1. Data/ report on in-vitro dose calculation of drug Oseltamivir for the proposed indication and justification for the proposed dose in the pilot study. 2. Detail of in-vitro cell lines (Squamous or adenocarcinoma cells). Further, the study should be performed in small number of subjects involving 10-20 patients. Accordingly, applicant should submit revised research study protocol for further review by the committee.
9.	ND/IMP/23/000078 Capivasertib film coated tablets 160 mg and 200 mg (TRUQAP)	M/s. AstraZeneca Pharma India Limited	In light of earlier SEC recommendation dated 21.08.2024 & 22.08.2024, firm re-deliberated their proposal for grant of permission to import and marketing of the Capivasertib film-coated tablets 160 mg and 200 mg (TRUQAP) along with justification for local Phase III Clinical Trial waiver before the committee. After detailed deliberation the committee noted that ongoing global clinical trials are in different indication. The committee noted the various side effects presented by firm in ongoing trials and requested to present the Indian subset safety analysis. Accordingly, firm needs to submit the causality assessment of SAE/AE and patient outcome in these cases for further deliberation.