Recommendations of the SEC (Oncology) made in its 04th/26 meeting held on 04.02.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/176/25 Online Submission (53390) BMS-986365 (CC-94676)	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented phase III clinical study protocol no. CA0711000, amendment 01 dated 10 September 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.
2.	CT/179/25 Online Submission (53621) Ficerafusp Alfa (BCA101)	M/s. IQVIA RDS (India) Private Limited	The firm presented phase II/III clinical study protocol no. BCA101X301, version 2.0 dated 04 November 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) More government site shall be included in the study 3) Day care center should not be a part of clinical trial.
3.	CT/182/25 Online Submission (53631) BMS-986504	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented phase II/III clinical study protocol no. CA2400030, amendment 01 dated 24 June 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) Increase the Number of subjects from India. 3) More government site shall be included in the study 4) Day care center should not be a part of clinical trial.
4.	CT/13/26 Online Submission (54486) DAK539 (Pelabresib)	M/s. Novartis Healthcare Private Limited	The firm did not attend the meeting.

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5.	CT/85/25 Online Submission (50243) Lisaftoclax (APG-2575)	M/s. IQVIA RDS (India) Private Limited	In light of earlier SEC recommendation dated 29.07.2025, the firm presented phase III clinical study protocol no. APG2575AG301 version no. 1.2 (EU) dated 16 April 2025. Now the firm presented phase I & II study report including safety data, global approval status of the drug with indication, prescribing information, etc. 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) More government site shall be included in the study
Medical Devices Division			
6.	File No. MED-14/2/2026-eoffice AI-based mammogram triage software	Dr. Krithika Rangarajan, Associate Professor, Department of Diagnostic and Interventional Oncoradiology, AIIMS, New Delhi	The applicant presented their proposal for conducting academic study on the applied device i.e. AI-based mammogram triage software, indicated for use to perform triage in a high-risk screening (clinical) setting by analysing and interpreting mammograms (DICOM radiological images) for the presence of breast cancer lesions. After detailed deliberation, the committee recommended for conducting the proposed study.
Biological Division			
7.	e-Receipt No. E-117630 Denosumab 120 mg	M/s. Reliance Life Sciences Pvt. Ltd.	The firm presented the final CSR of Phase IV clinical trial titled "A Prospective, multi-centre, single arm, open label Phase IV clinical study to evaluate safety and efficacy of DenosuRel^{TM} containing Denosumab manufactured by Reliance Life Sciences, Pvt. Ltd. India for prevention of skeletal related events in patients with bone metastases from solid tumours" conducted vide Protocol No. RLS/PMS/2021/01, Version 1.0 dated 26.02.2021. After detailed deliberation, the committee noted the results of the study presented by the firm.

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8.	e-Receipt No. E-120003 Denosumab Solution for injection 120 mg/1.7 mL (70 mg/ml)	M/s. Intas Pharmaceuticals Limited	The firm presented the final CSR of Phase IV clinical trial titled "A prospective, single-dose, Interventional, Single Arm, Multi-Centre, Phase IV Study to Assess Safety, Efficacy and Immunogenicity of Denosumab in Patients with Bone Metastases from Advanced Malignancies" conducted vide Protocol No. 0399-21, Version No.: 02 dated 08 Jul 2022. After detailed deliberation, the committee noted the results of the study presented by the firm.