Recommendations of the SEC (Oncology) made in its 13th/26 meeting held on 06.05.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/46/26 Online Submission (55674) BMS-986545/ PUMITAMIG	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented phase III clinical study protocol no.: CA2660002 version no. Original Protocol dated 09-DEC- 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition. 1) More geographically distributed government site shall be included in the study. 2) Day care of centers should not a part of clinical trial. 3) All PI shall be Medical Oncologist only.
2.	CT/62/26 Online Submission (56377) AMN1126	M/s. Amneal Pharmaceuticals Pvt. Ltd.	The firm presented phase IIa clinical study protocol no.: AMN1126-201-25 version no. 1.0 dated 08-APR-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the IDSMB shall closely monitor safety and submit quarterly report to the Ethics Committee and CDSCO.
Biological Division			
3.	Receipt No.E-125472 Pertuzumab-Trastuzumab Injection 600 mg+600 mg [10 ml/15ccvial] and 1200 mg+600 mg vial [15 ml/20 cc vial] (Phesgo®)	M/s. Roche Products (India) Pvt. Ltd.	The firm did not attend the meeting.
4.	Receipt No. E-125293 Atezolizumab subcutaneous Injection (1875 mg/15 mL vial)	M/s. Roche Products (India) Private Limited.	The firm presented the proposal of update in Package Insert Version 2.0 dated Nov 2025 for Atezolizumab subcutaneous Injection (1875 mg/15 mL vial). After detailed deliberation, the committee recommended the proposal of Update of Package Insert Version 2.0 dated Nov 2025 for Atezolizumab subcutaneous Injection (1875 mg/15 mL vial).

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5.	BIO/CT21/BO/2025/51995 Filgrastim Injection 300 mcg/0.5 and 480 mcg/0.5 mL	CuraTeQ Biologics Private Limited	The firm presented the proposal for grant of permission to manufacture and market the Filgrastim Injection 300 mcg/0.5 mL & 480 mcg/0.5 mL in prefilled syringe based on the results of Phase-I clinical trial (BP13-102) conducted on 300 mcg/0.5ml to establish the comparative pharmacokinetic, pharmacodynamic, safety and immunogenicity of the drug product using absolute neutrophil count (ANC) as validated PD marker. The committee noted that the primary PD parameters study results does not meet the pre-approved protocol criteria. The committee also noted that firm has not submitted any clinical data on Indian population with respect to 480mcg/0.5ml strength. After detailed deliberation, the committee has not recommended for grant of permission to manufacture and market Filgrastim Injection 300 mcg/0.5 mL & 480 mcg/0.5 mL in prefilled syringe for the applied indications.
6.	BIO/CT21/FF/2026/54188 Bevacizumab concentrate for solution for infusion 25 mg/ml	M/s. Dr Reddy's Laboratories Limited.	The Firm presented the following additional indication of the drug Bevacizumab concentrate for solution for infusion 25 mg/ml by the way of extrapolation in line with indication approved for innovator product based on prescribing information. "Bevacizumab in combination with atezolizumab for the treatment of patients with unresectable or metastatic Hepatocellular Carcinoma (HCC) who have not received prior systemic therapy". After detailed deliberation, the committee recommended for approval of the applied additional indication that are already approved for innovator product in India subject to the condition that firm shall conduct Phase IV study in the country for the approved indication. Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission to manufacture

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			and market the product.
New Drug Division			
7.	ND/CT/26/000014 Lutetium Lu 177 vipivotide tetraxetan solution for injection or infusion 1000 MBq/mL	M/s. Novartis Healthcare Private Limited	In line with the condition of permission for import and market of the drug, Lutetium Lu-177 Vipivotide Tetraxetan solution for injection or infusion 1000 MBq/mL, the firm presented Phase IV clinical trial protocol (Protocol Number: CAAA617A0IN01, Version No: V00, dated 20-Feb-2026) before the committee. After detailed deliberation, committee opined that firm should revise the Phase IV CT protocol considering the following points: 1. Firm should revise the sample size based on unexpected AEs 2. Firm should increase the duration of study to be able to capture skeletal event end points 3. Firm should revise the objective of the study and to include participants with ECOG status 2 Accordingly, firm should submit the revised Phase-IV CT protocol to CDSCO within one month for further review by the committee.
SND Division			
8.	SND-11011/6/2026-eoffice Ibrutinib Capsules 140 mg	M/s Jhonson and Jhonson	Firm presented their proposal for updation of Efficacy and Safety information in prescribing information of Ibrutinib Capsules 140 mg before the committee. After detailed deliberation, the committee considered the proposed updates in the prescribing information as presented by the firm.