Recommendations of the SEC (Oncology) made in its 01th/26 meeting held on 07.01.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/165/25 Online Submission (52995) AZD5335	M/s. Fortrea Development India Private Limited	The firm presented phase III clinical study protocol no. D8991C00001 version 1.0 dated 19 August 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more government site shall be included in the study.
Biological Division			
2.	BIO/CT04/FF/2025/48266 Pegfilgrastim 6 mg/0.6 mL on body injector.	M/s. Syngene International Limited.	In light of earlier SEC recommendation dated 17.07.2025, the firm presented the recommended data on the in-use stability and functionality & performance evaluation of Pegfilgrastim 6 mg/0.6 mL on body injector. The committee has noted that proposed drug Pegfilgrastim in prefilled syringes (PFS) is approved in more than 45 countries including USA, EU, Canada, Australia, and Switzerland. The committee further noted that current application for conduct of Phase I clinical trial titled "A Randomized, Open-label, Single-dose, Three-period, Two-treatment, Three-sequence, Partial Replicate Crossover Study to Compare the Pharmacokinetics, Pharmacodynamics, Safety and Tolerability of Fulphila OBI kit and Fulphila PFS (pegfilgrastim) for manual use in Normal Healthy Male Volunteers, as per protocol number SYNCD-052-24/ BIO-PEGFIL-102 Version-2.0 dated-05-Jun-2025 pertains to a line extension of an already approved product in EU and USA. Accordingly, the committee

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			recommended grant of permission to conduct the Phase I clinical trial for export purpose as per the protocol presented by the firm.
3.	BIO/CT18/FF/2025/51752 Durvalumab Solution for Infusion 120 mg/2.4 mL and 500 mg/10 mL	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for grant of approval of following additional indication of the drug Durvalumab Solution for Infusion 120 mg/2.4 mL and 500 mg/10 mL aligned with USFDA approval along with a request for a local clinical trial waiver:- Durvalumab in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT) chemotherapy as neoadjuvant and adjuvant treatment, followed by single-agent Durvalumab, is indicated for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC)**.** The committee noted the drug Durvalumab Solution for Infusion 120 mg/2.4 ml & 500 mg/ 10 ml (IMFINZI) is approved in India since Jun-2018 and till date 409 Indian patients have participated in 18 global clinical trials of Durvalumab. Additionally, 01 Local Phase IV has been completed in the indication locally advanced, unresectable non-small cell lung cancer (NSCLC) indication involving 100 patients. Further, the committee noted that the proposed indication is approved in USA. After detailed deliberation, the committee recommended for grant of approval for the proposed additional indication with a condition to conduct Phase IV study in India in proposed Indication. Accordingly, the firm shall submit the India specific Phase IV protocol to

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			CDSCO within 03 months of the grant of permission for this additional indication.
New Drug Division			
4.	ND/163/2025-eoffice Olaparib versus Capecitabine	Dr. Sheila Myatra, IRB, Tata Memorial Hospital, Mumbai	The study investigator presented protocol titled" A randomized, phase 2 study to investigate the efficacy and tolerability of Olaparib versus Capecitabine in patients with BRCA or HRD positive platinum response advance gastric adenocarcinomas (MOBAG trial)" (IEC project number: 4869) before the committee. After deliberation, the committee recommended that Principle Investigator should submit review report of scientific committee of IEC, clearly reflecting the conclusion and recommendation w.r.t. the proposed study. The committee also opined that EC should clearly state the reason for referring the proposal to CDSCO.
5.	ND/CT/25/000031 Brigatinib Tablets 30 mg, 90 mg & 180 mg	M/s. Takeda Biopharmaceuticals India Pvt. Ltd.	In the light of earlier SEC recommendation dated 08.07.2025, the firm presented revised Phase-IV CT protocol (Protocol no. Brigatinib-4006, Version No.: 1.0 and Date 10-September-2025), before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial as per the protocol presented with condition that firm should provide post-trial access to trial patients.
6.	12-05/2014-DC (E-18806) Enzalutamide 40 mg soft Capsule	M/s. Astellas Pharma India Pvt Ltd	In light of earlier SEC recommendation dated 28.08.2025, firm presented updated prescribing information, incorporating Phase IV study and SAEs outcome of Enzalutamide 40 mg soft Capsule, before the committee.

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			After detailed deliberation, the committee considered the updated prescribing information (Version No. 9 dated 10 Dec 2025).
SND Division			
7.	SND/CT21/FF/ 2023/38264 Ibrutinib tablet 140 mg, 280 mg, 420 mg & 560 mg	M/s. Natco Pharma Limited	The firm did not attend the meeting.
8.	SND/CT/25/000055 Amlodipine tablets 10 mg (Additional indication)	M/s. Raptim Research Pvt. Ltd	In light of earlier SEC recommendation dated 23.09.2025 & 14.10.2025, the firm presented the proof of concept study protocol before the committee. After detailed deliberation, the committee recommended to conduct Phase-II pilot study as per the protocol no: CT/24/009 dated 08.12.2025 presented by the firm with following conditions: 1. Interim safety data of first 25 patients will be submitted to CDSCO for deliberation before SEC. Thereafter interim report every 6 months shall be submitted to CDSCO for review by the committee. 2. Patient shall be provided with digital sphygmomanometer to monitor Blood Pressure.