Recommendations of the SEC (Oncology) made in its 01st/25 meeting held on 09.01.25 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/130/23 Online Submission (36238) Volrustomig (MEDI5752)	M/s Astrazeneca Pharma India Limited	The firm presented protocol amendment version 3.0 dated 21 May 2024 protocol no. D798AC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/150/23 Online Submission (36265) GSK 4057190A/ Dostarlimab	M/s GSK Pharma India Private Limited	The firm presented protocol amendment 2 dated 26 August 2024 protocol no. 221530. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/153/23 Online Submission (36367) Repotrectinib (BMS-986472,TPX-0005)	M/s Bristal Myers Squibb India Private Limited	The firm presented protocol amendment 01 dated 18 September 2024 protocol no. CA127-1030. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
4.	BIO/CT18/FF/2024/45384 Durvalumab solution for infusion 120mg/2.4mL and 500 mg/10mL	M/s. Astra Zeneca Pharma India Limited	The firm presented the proposal for grant of approval of additional indication of the drug Durvalumab solution for infusion 120mg/2.4ml and 500mg/10ml i.e. "Durvalumab is indicated for the treatment of patients with limited-stage small cell lung cancer (LS-SCLC) whose disease has not progressed following platinum-based chemoradiation therapy (CRT)" based on the data generated from ongoing Phase III Global Clinical Trial where India is one of the participating country. The committee noted that the proposed indication is approved in USA and only negligible number of subjects are included in the trial from India. After detailed deliberation, the committee recommended for grant of approval for

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			the proposed additional indication with a condition to conduct Phase IV Clinical trial. Accordingly, the firm shall submit the Phase IV protocol to CDSCO within 03 months of the grant of permission for additional indication.
5.	BIO/CT18/FF/2024/45651 Amivantamab Liquid Concentrate for Infusion 350 mg	M/s Johnson and Johnson Pvt. Ltd	The firm presented the proposal for grant of approval of additional indication of the drug Amivantamab Liquid Concentrate for infusion 350 mg i.e. "Amivantamab in combination with carboplatin and pemetrexed for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer(NSCLC) with activating epidermal-growth factor receptor (EGFR) Exon 20 insertion mutations" based on the data generated from Phase III Global Clinical Trial where India is one of the participating country. The committee noted that the proposed indication is approved in US, EU, UK and Japan. After detailed deliberation, the committee recommended for grant of approval for the proposed additional indication.
6.	BIO/CT04/FF/2024/45915 Enfortumab vedotin solution for injection 30mg	M/s Klinera Global Services	The firm presented the proposal for grant of permission to conduct Phase IV clinical trial titled" A Multicenter, Phase 4, Open - label, Single -arm, Safety Study of Enfortumab Vedotin in Adult Indian Participants with Previously Treated Locally Advanced or Metastatic Urothelial Cancer" vide protocol No. 7465-CL-4001 Amendment No. 01 dated 06.12.2024. After detailed deliberation, the committee recommended for approval to conduct the study as per the protocol presented by the firm.
New Drug Division			
7.	ND/MA/22/000104	M/s Alkem	In light of earlier SEC recommendation dated 25.11.2022, the firm presented the

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	Ferric Maltol Capsule 30 mg	Laboratories Ltd.	BE study report for grant of permission to manufacture and market of Ferric Maltol Capsule 30 mg indicated in adult for the treatment of iron deficiency before the committee. After detailed deliberation, the committee opined that iron deficiency is not unmet medical need and hence the committee did not recommend for the phase III clinical trial waiver. Accordingly, the committee recommended that firm should conduct the phase III clinical trial and submit the phase III CT protocol for further review by the committee.
8.	ND/MA/24/000032 Tucatinib Tablets 50mg & 150mg	M/s MSN Laboratories Private Limited	The firm presented proposal for grant of permission to manufacture and market of Tucatinib Tablets 50mg and 150mg, along with BE study report and justification for local Phase III Clinical Trial wavier, before the committee. After detailed deliberation, the committee opined on BE study that the firm need to submit side effects profile, time versus concentration data of all subjects who participated in the study, and inter-subject variability data. Also, the committee opined that the firm should submit the detailed literature on Phase-III clinical trial report of Tucatinib Tablets for Metastatic Breast Cancer and Unresectable or Metastatic Colorectal Cancer. Accordingly, the firm submit the above data to CDSCO, for further review by the committee.
Medical Devices Division			
9.	CI/MD/2023/113223 Zidan Medical Radiofrequency Ablation System	M/s PAREXEL International Clinical Research Private Limited	The firm withdrawn the proposal.