Recommendations of the SEC (Oncology) made in its 08th/25 meeting held on 11.03.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/74/17 Online Submission (37395) Duvralumab (MEDI4736) and Tremelimumab	M/s Astrazeneca Pharma India Limited	The firm presented protocol amendment version 8.0 dated 17 June 2024 protocol no. D419CC00002. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/76/23 Online Submission (37419) Iberdomide	M/s Bristol-Myers Squibb India Private Limited	The firm presented protocol amendment 2.0 dated 29 Oct 2024 protocol no. IM048022. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/11/25 Online Submission (47670) Disitamab Vedotin	M/s Pfizer Limited	The firm presented phase 3 clinical study protocol no: C5731001 amendment 03 dated 03-December-2024. 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 sites shall be included in the study. 2. PI shall be Medical Oncologist only.
4.	CT/13/25 Online Submission (47750) ABL001 (Asciminib)	M/s Novartis Healthcare Private Limited	The firm presented phase IIIb clinical study protocol no. CABL001A2001B Version number: 03 dated 17 May 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
5.	E-64796 Durvalumab solution for infusion 120mg /2.4ml and 500 mg/10ml	M/s Astrazeneca Pharma Private Limited	The firm did not turn up for the Presentation.
6.	BIO/CT18/FF/2024/46257 Amivantamab Liquid Concentrate for Infusion 350 mg(rDNA origin)	M/s Johnson and Johnson	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 is indicated in combination with carboplatin and pemetrexed for the treatment of patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with osimertinib" based on the clinical 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, Switzerland and Australia. After detailed deliberation, the committee recommended for approval for the proposed additional indication with condition to conduct Phase IV study. Accordingly, the firm should submit Phase IV study protocol within three months of approval of additional indication.
SND Division			
7.	SND/IMP/24/000061 Osimertinib Tablets 40 mg and 80 mg (Additional indication)	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for grant of permission to import and market Osimertinib tablets 40mg and 80 mg (additional Indication) along with Global Clinical Trial data before the committee. The firm has informed that the proposed drug Osimertinib tablets 40mg and 80 mg already approved in the country on 29.05.2017, 03.08.2018 and 09.03.2021 for other indications. The firm has also informed that Osimertinib tablets 40mg and 80 mg for

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			the proposed indication is already approved in United States, European Union (27 Member States), Switzerland, Australia, South Korea and China. After detailed deliberation, the committee recommended for grant of permission to Osimertinib tablets 40mg and 80 mg for the proposed additional indication with subject to condition that the firm should conduct Phase-IV clinical trial study. Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee.
8.	SND/MA/24/000238 Aprepitant powder for Oral Suspension 125 mg	M/s Zydus Lifesciences Limited	The firm presented the proposal for grant of permission to manufacture and market Aprepitant powder for Oral Suspension 125 mg along with BE protocol and justification for CT study waiver. The firm informed that the Aprepitant powder for Oral Suspension 125 mg is already approved in USA, EU & UK and Aprepitant capsules 40mg/80mg/125mg are already approved in India. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the protocol presented by the firm. Accordingly, the firm should submit BE study report to CDSCO for further review by the committee. Further, decision on the Phase III clinical trial may be taken after review of BE study results.