Recommendations of the SEC (Oncology) made in its 22nd/24 meeting held on 20.11.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/CT04/FF/2024/45722 Online Submission (45722) Pembrolizumab (CT-P51)	M/s Syneos Health India	The firm presented phase 3 clinical study protocol no. CT-P51 3.1 amendment 3 version 1.3 dated 11 September 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	GCT/PostAppr/2024/35603 Online Submission (35603) Pertuzumab andTrastuzumab	M/s Roche	The firm presented protocol amendment version 3.0 dated 25 January 2024 protocol no. MO43110. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	GCT/PostAppr/2024/35477 Online Submission (35477) Datopotamab deruxtecan	M/s Astrazeneca Pharma India	The firm presented protocol amendment 5 version 6.0 dated 29 August 2024 protocol no. D9268C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	GCT/PostAppr/2024/35478 Online Submission (35478) Volrustomig (MEDI5752)	M/s Astrazeneca Pharma India	The firm presented protocol amendment version 4.0 dated 03 September 2024 protocol no. D7984C00002. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	GCT/PostAppr/2024/35697 Online Submission (35697) ABL001 (Asciminib)	M/s Novartis	The firm presented protocol amendment version 02 dated 04 September 2024 protocol no. CABL00IJI2302. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
6.	GCT/CT04/FF/2024/46194 Online Submission (46194) Eftilagimod Alfa	M/s Fortrea	The firm presented phase 3 clinical study protocol no. TACTI-004 version 1.1 dated 06-SEP-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that regulatory authority approval or rejection (with reasons) should be intimated to CDSCO immediately. (Dr. Kalyan Kusum Mukherjee didn't participate.)

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
7.	GCT/PostAppr/2024/35814 Online Submission (35814) JDQ443	M/s Novartis	The firm presented protocol amendment version 04 dated 24 September 2024 protocol no. CJDQ443B12301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
8.	SND/MA/24/000034 Enzalutamide 80mg tablet	M/s Intas Pharma	The firm presented the proposal for grant of permission to manufacture and marketing of Enzalutamide Tablet 80 mg along with BE study reports in fasting and fed condition before the committee. Firm has informed that Enzalutamide capsules 80 mg are approved in India (Year 2020) and Enzalutamide tablet 80 mg is also approved in US (Year 2020) and in Europe (Year 2013). After detailed deliberation, the committee recommended for grant of permission to manufacture and market Enzalutamide Tablet 80 mg for proposed indication with subject to condition that the firm should conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV CT protocol within 03 months from the date of approval of the drug to CDSCO for further review by the committee.