Recommendations of the SEC (Oncology) made in its 17th/24 meeting held on 05.09.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/96/24 Online Submission (44486) Datopotamab deruxtecan (DATO-DXD, DS-1062) Osimertinib	M/s. Parexel International Clinical Research Private Limited	The firm presented Phase 3 clinical trial study protocol no. D516KC00001 version no. 1.0 dated 26 March 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the condition that: 1. Investigator should be Medical Oncologist only. 2. More geographically distributed Govt. sites shall be included in the study.
2.	CT/59/22 Online Submission (34153) Ceralasertib (AZD6738) and Durvalumab (MEDI4736)	M/s. Parexel International Clinical Research Private Limited	The firm presented protocol amendment 1.0, version 2.0 dated 19 December 2023, protocol no. D533BC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/44/21 Online Submission (34271) Atezolizumab Injection 1200mg/20ml	M/s. Roche Products (India) Private Limited	The firm presented protocol amendment version 5 dated 08 May 2024, protocol no. WO42633. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/07/23 Online Submission (34223) HT-6184 2 mg capsule	M/s CBCC Global Research LLP	The firm presented protocol amendment version 4.0 dated 01 July 2024, protocol no. HT-6184-MDS-001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/131/22 Online Submission (34222) PF-06741086 (Marstacimab) Solution for Injection	M/s Pfizer Limited	The firm presented the proposal to increase the number of subjects from 10 to 16 vide approved protocol number B7841008. After detailed deliberation, the committee recommended for approval to increase in number of subjects from 10 to 16 as presented by the firm.
6.	CT/98/24 Online Submission (44659)	M/s AstraZeneca Pharma India Limited	The firm presented Phase 3 clinical trial study protocol no. D9722C00001 version no. 2.0 dated 30 January 2024.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Saruparib (AZD5305) 20mg, Camizestrant 75mg,		After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the condition that Investigator should be a Medical Oncologist only.
7.	CT/155/22 Online Submission (34355) Pembrolizumab 200mg + Vibostolimab 200mg	M/s MSD Pharmaceuticals Private Limited	The firm presented protocol amendment 04, dated 27 June 2024, protocol no. MK7684A-10. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
8.	CT/17/22 Online Submission (34367) 1. Durvalumab (MEDI4736) 500mg/Vial + 2. Domvanalimab (AB154) 300 mg/ vial	M/s AstraZeneca Pharma India Limited	The firm presented protocol amendment, version 5.0 dated 24 May 2024, protocol no. D9075C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
9.	BIO/CT04/FF/2024/44143 Toripalimab Injection (r-DNA origin) 240mg/6mL	M/s. Dr. Reddy's Laboratories Limited	The firm presented the Phase IV study protocol titled "A phase 4, multi center, non comparative, open-label, two cohort study evaluating the safety and efficacy of intravenously administered toripalimab in the treatment of Indian patients with recurrent or metastatic nasopharyngeal carcinoma" vide protocol No. TP-02-001 Version 1.0 dated 19 Jun 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per the protocol presented by the firm with the condition to increase the number of subjects from 15 to 25 in each cohort. Accordingly, the firm should submit the revised protocol to CDSCO for further evaluation.
BA/BE Division			
10.	BABE/CT05/FF/2024/43065 FDC of Aprepitant 130mg and Palonosetron 0.25mg	M/s Veeda Clinical Research Limited	The firm presented the Protocol No.: 23-VIN-0518 Version No. 01 Protocol Date 22-MAR-2024 for BA/BE study of FDC of Aprepitant 130mg and Palonosetron 0.25mg HCL injectable emulsion 18ml for export purpose only.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	HCL injectable emulsion 18ml		The committee noted that the individual formulation of Aprepitant 130 mg/18 ml (7.2mg/ml) injectable Emulsion (IV) and Palonosetron Hydrochloride EQ 0.25mg BASE/5ml injectable (IV) is approved in USA. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.