Recommendations of the SEC (Oncology) made in its 14th/24 meeting held on 09.07.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/72/24 Online Submission (43338) KSHN001126 200 mg/1.11 mL (eq. to 228mg of KSHN001126 fumarate) Oral Solution	M/s. Shivanka Research Private Limited	The firm presented phase 1a clinical study Protocol no. CE-24-02 version 2.0 dated 09 .05 2024 After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/68/24 Online Submission (43277) MK-1084	M/s. MSD Pharmaceuticals Private Limited	The firm presented phase 3 clinical study protocol no. MK-1084-004 version 00 dated 15 December 2023. After detailed deliberation the committee opined that the firm should submit details of AE and SAE data for further review by the committee.
3.	CT/67/24 Online Submission (43257) GSK4428859A (Belrestotug), GSK4057190 (Dostarlimab)	M/s. GSK Pharma India Private Limited	The firm presented phase 3 clinical study protocol no. 213823 dated 09 January 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm
4.	CT/66/24 Online Submission (43135) CC-92480 (BMS-986348), Mezigdomide	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented phase 3 clinical study protocol no. CA057001 version 04 dated 10 May 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm
5.	CT/50/24 Online Submission (42642) Ribociclib	M/s. Novartis	The firm didn't turn up for presentation.
6.	CT/155/22 Online Submission (32220) Vibostolimab with	M/s. MSD	The firm has withdrawn this application.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Pembrolizumab		
7.	CT/92/22 Online Submission (32970) Teclistamab & Talquetamab	M/s. Johnson and Johnson Private Limited	The firm has withdrawn this application.
8.	CT/115/23 Online Submission (32866) Capivasertib (AZD5363)	M/s. AstraZeneca Pharma India Limited	The firm presented protocol amendment 5 version 6.0 dated 05 March 2024 protocol no. D361DC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
9.	CT/119/23 Online Submission (32896) SB27 (proposed Pembrolizumab biosimilar)	M/s. Fortrea Development India Private Limited	The firm presented protocol amendment version 2.0 dated 06 December 2023 protocol no. SB27-3004. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
SND Division			
10.	SND/CT/24/000010 Relugolix Tablets 120mg	M/s. Zydus Life Sciences Limited	The firm presented the proposal for grant of permission to conduct Phase-IV clinical trial of Relugolix 120mg Tablets along with Phase-IV clinical trial protocol (Protocol No. 24-01, Version:00, Dated:12.01.2024) before the committee. The firm has informed that CDSCO already issued permission vide no. MF-ND-54/2023 dated 16.10.2023 for manufacture and marketing of Relugolix 120mg Tablets in the country with condition to conduct Phase-IV clinical trial. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-IV clinical trial of Relugolix 120mg Tablets as per protocol presented by the firm.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
11.	SND/MA/24/000052 Abiraterone Tablets 1000mg (Additional strength)	M/s. MSN Labs Private Limited	The firm presented the proposal for grant of permission for manufacture and marketing of Abiraterone Acetate film coated tablets 1000mg along with bioequivalence protocol and justification for waiver of Phase-III clinical trial before the committee. The firm has informed that CDSCO has already approved lower strength of Abiraterone Acetate 250mg and 500mg for applied indication in the year 2011 and 2018 in the country. Further, the firm has informed that proposed formulation of Abiraterone Acetate tablets 1000mg is already approved in Europe in the year 2021. After detailed deliberation, the committee recommended for the grant of permission to conduct bioequivalence study as per protocol presented by the firm and submit BE study report along with clinical data to CDSCO for further consideration by the committee.
12.	SND/IMP/24/000038 Olaparib film-coated Tablets 100mg and 150mg for additional indication	M/s. AstraZeneca Pharma India Limited	The firm didn't turn up for presentation.
New Drugs Division			
13.	ND/CT/23/000100 Asciminib film-coated tablets	M/s. Norvartis Healthcare Pvt. Ltd.	The firm presented the proposal for Phase IV clinical trial protocol of Asciminib film-coated tablets 20 mg and 40mg. After detailed deliberation, the committee recommended for conduct of Phase IV clinical study as per the presented protocol. Further, the committee opined that it may be desirable to add more Government sites.