Recommendations of the SEC (Oncology) made in its 16th/24 meeting held on 21.08.2024 & 22.08.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/88/24 Online Submission (44028) LY3537982	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd.	The firm presented phase 3 clinical trial protocol no. J3M-MC-JZQB version (e) dated 12 APR 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with the condition that PI shall be Medical Oncologist only.
2.	CT/25/23 Online Submission (33752) Camizestrant	M/s. Fortrea Development India Private Limited	The firm presented protocol amendment version 4.0 dated 11 March 2024 protocol no. D8531C00002 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/07/21 Online Submission (33959) AZD9833	M/s. AstraZeneca Pharma India Limited	The firm presented protocol amendment 5.0, version 6.0 dated 16 May 2024 protocol no. D8532C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/37/22 Online Submission (33978) Hafnium Oxide PO4 Water for Injection	M/s. Pharmaceutical Research Associates India Private Limited	The firm presented protocol amendment 5 version 6.0 dated 28 May 2024 protocol no. NANORAY-312. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/140/23 Online Submission (34015) Nivolumab	M/s. Dr. Reddy's Laboratories Limited	The firm presented increasing the number of patients in India from 150 to 241 protocol no. NU-01-001 After detailed deliberation, the committee recommended for approval of increase in the patients in India from 150 to 241 as presented by the firm.
Biological Division			
6.	BIO/CT18/FF/2022/ 35249 Ipilimumab 5mg/ml Concentrate for solution for infusion	M/s. BMS	In light of earlier SEC recommendations dated 08.06.2023, 10.10.2023 and 09.11.2023 & 10.11.2023, the firm presented the CSR of the Phase IV study conducted in India for RCC indication along with the request for waiver of Phase IV study for the proposed

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			indication of ESCC. After detailed deliberation, the committee reiterated the recommendations of SEC meeting dated 10.10.2023 which is as follows- "The committee recommended for grant of additional indication i.e., Ipilimumab in combination with Nivolumab for first line treatment of adult patients with unresectable advanced or metastaticesophageal squamous cell carcinoma (ESCC) with the condition that the firm should conduct Phase IV study for the proposed indication in India." Accordingly, the firm should submit Phase IV protocol within three months of approval of additional indication.
7.	BIO/CT04/FF/2024/ 43718 Pertuzumab Concentrate for solution for Infusion 420 mg/14 mL (30mg/mL)	M/s. Intas Pharmaceutical Ltd.	The firm presented the protocol to conduct Phase I study for Pertuzumab Concentrate for solution for Infusion 420 mg/14 mL titled "A randomized, double-blind, three-arm, balanced, single-dose, parallel-group study comparing pharmacokinetics of Pertuzumab (420 mg solution for Infusion)of Intas Pharmaceuticals Limited, India with Perjeta® of Genentech Inc, A member of Roche Group, USA and Perjeta of Roche Pharma AG, Germany in normal, healthy, adult, human male subjects" vide Protocol no. 0141-24,Version: 1.0 dated 10-May-2024. After detailed deliberation, the committee recommended for approval of study as per the presented protocol.
SND Division			
8.	SND/IMP/24/000046 Pegylated liposomal irinotecan 4.3 mg/ml concentrate for dispersion for infusion	M/s. Servier India Private Limited	The firm did not turn up for presentation.
9.	SND/IMP/24/000056 Alectinib Capsules 150 mg	M/s. Roche Products (India) Pvt. Ltd.	The firm presented their proposal for addition of indication "Alecensa as monotherapy is indicated as adjuvant treatment following complete tumour resection for adult patients with ALK-

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			positive NSCLC at high risk of recurrence" for Alectinib capsules 150mg with local Phase III and Phase IV clinical trial waiver before the committee. The firm has informed that Alectinib capsules 150mg is already approved by CDSCO on 23.01.2017 for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Crizotinib and on 05.03.2018 for the indication" First line treatment of patients with Anaplastic Lymphoma Kinase (ALK)-positive locally advanced or metastatic non- small cell lung cancer (NSCLC). Further, firm has informed that Alectinib capsules 150mg is already approved in USA on 18.04.2024 and European Union on06.06.2024 for the same indication. The firm has presented the clinical trial report of ongoing Global Phase III clinical trial (ALINA) in support of the indication to the committee. After detailed deliberation, the committee opined that there is a unmet medical need. Therefore, the committee recommended for the approval of the applied drug for the condition "as monotherapy is indicated as adjuvant treatment following complete tumour resection for adult patients with ALK-positive NSCLC at high risk of recurrence" with the condition that the firm should conduct local Phase IV clinical trial. Accordingly, the firm should submit Phase IV study protocol to CDSCO within 03 months from the date of approval of the drug product for further review by the committee.
New Drugs Division			
10.	ND/IMP/23/000078	M/s. AstraZeneca Pharma India Ltd	The firm has presented proposal for grant of permission to import and market

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	Capivasertib film-coated tablets 160mg and 200mg (TRUQAP)		Capivasertib film coated Tablets 160mg and 200mg (TRUQAP), along with a justification for local Clinical Trial waiver before the Committee. After detailed deliberation, the committee did not recommend the waiver of local clinical trial, as there is no safety data in Indian population and other global clinical trials are ongoing.
11.	ND/IMP/24/000020 Pyrotinib Maleate tablets 80mg	M/s. Dr. Reddy's Laboratories Limited	The firm has presented proposal for grant of permission to import and market Pyrotinib Maleate Tablets 80mg, along with Phase III Clinical Trial protocol, before the Committee. After detailed deliberation, the committee opined that the firm should submit the suitable comparative arm as standard of care, for further review by the committee.
12.	ND/MA/24/000089 Lurbinectedin for Injection 4mg/Vial	M/s. MSN Laboratories Private Limited	The firm has presented its proposal for grant of permission to manufacture and market of new drug Lurbinectedin Injection 4mg/vial along with the local Clinical Trial Waiver and Bio-equivalence study waiver before the Committee. After detailed deliberation, the committee did not recommend waiver of local Clinical Trial and Bio-equivalence study and opined that firm should conduct Phase III clinical trial in Indian population. Accordingly, firm should submit Phase III clinical Trial protocol and Bio-equivalence study protocol to CDSCO for further review by the committee.