Recommendations of the SEC (Oncology) made in its 13th/24 meeting held on 18.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/30/22 Online Submission (32831) Capivasertib	M/s. Fortrea Development India Private Limited	The firm presented protocol amendment version 3.0 dated 24.07.2023 and protocol amendment version 4.0 dated 30 January 2024 protocol no. D361EC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/164/21 Online Submission (32717) Zanidatamab (ZW25) Tislelizumab (BGB-A317)	M/s. PPD Pharmaceutical Development India Pvt. Ltd.	The firm presented protocol amendment 4 dated 26.01.2024 protocol no. ZWI-ZW25-301. After detailed deliberation, the committee, recommended for protocol amendment as presented by the firm
3.	CT/123/21 Online Submission (32583) Rastuzumab deruxtecan (T-DXd, AZD4552)	M/s. Astrazeneca Pharma India Limited	The firm presented protocol amendment version 5.0 dated 15.04.2024 protocol no. D967RC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/76/21 Online Submission (31556) Savolitinib (AZD6094, HMPL-504, volitinib), Durvalumab (MEDI4736	M/s. Fortrea Development India Private Limited	The firm presented protocol amendment version 4.0 dated 08.09.2023 protocol no. D5086C00001 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
5.	CT/23/22 Online Submission (27951) MEDI 1123 Tremelimumab MEDI 4736 Durvalumab	M/s. AstraZeneca Pharma India Limited	In light of earlier SEC recommendation, the proposal was deliberated on 29.11.23 and 30.11.23, the firm presented protocol amendment version 2.0 dated 19 June 2023 protocol no D910VC00001 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with condition that 1.Approval letters from all the 17 countries shall be submitted to CDSCO 2. Interim analysis report after

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			completion shall be submitted to CDSCO.
6.	CT/76/20 Online Submission (28914) JNJ-61186372 (Amivantamab)	M/s. Johnson and Johnson Private Limited	In light of earlier SEC recommendation, the proposal was deliberated on 21.12.23 and 22.12.23, the firm presented protocol amendment 3 dated 07 August 2023 protocol no. 61186372NSC3001 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with the condition that interim analysis report before LTE Phase shall be submitted to CDSCO.
7.	CT/41/24 Online Submission (42313) Datopotamab deruxtecan (DS-1062a) 100mg/ vial Rilvegostomig (AZD2936) 750mg/vial (50mg/ml)	M/s. AstraZeneca Pharma India Limited	The firm presented phase 3 clinical study protocol no. D7632C00001 version 1.0 dated 30 October 2023 After detailed deliberation, the committee, recommended for grant of permission to conduct the trial as presented by the firm.
8.	CT/158/22 Online Submission (33905) Pralsetinib Capsules 100mg	M/s. Roche Products (India) Private Limited	In light of earlier recommendation, the proposal was deliberated in SEC on 19.03.2024 and 20.03.2024, the firm presented phase I-III clinical study protocol no. BQ42777 version 3.0 dated 15 August 2023. After detailed deliberation, the committee recommended for grant of permission to conduct phase-III clinical study as presented by the firm.
9.	CT/151/22 Online Submission (34938) Hydrogen peroxide	M/s. Prorelix Services LLP	The firm didn't turn up for presentation.
Biological Division			
10.	BIO/CT21/BO/ 2024/42760 Nivolumab 10mg/mL solution for i.v. infusion	M/s. Zydus Life Sciences	The firm presented their proposal for grant of permission to manufacture and market Nivolumab 10mg/mL liquid solution for intravenous infusion based on the results of comparative Phase III clinical trial conducted in India to

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			establish the efficacy, safety, pharmacokinetics and immunogenicity of the drug product in locally advanced or metastatic non-small cell lung cancer (NSCLC). After detailed deliberation, the committee recommended for grant of permission to manufacture and market Nivolumab 10mg/mL liquid solution for intravenous infusion for the indication locally advanced or metastatic non-small cell lung cancer (NSCLC). Further firm has also presented proposal for approval of additional indications by the way of extrapolation in line with indications approved for innovator product based on prescribing information. After detailed deliberation, the committee recommended for approval of the applied additional indications that are already approved for innovator product in India subject to the condition that firm shall conduct Phase IV study in the country for all approved indications including locally advanced or metastatic non-small cell lung cancer (NSCLC). Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission to manufacture and market the product.
SND Division			
11.	SND/CT/24/000009 Temozolomide powder for oral suspension 20mg/ml (300mg/15ml)	M/s. Intas Pharmaceuticals	The firm presented their proposal for grant of permission to conduct of palatability study (Acceptability, Taste & Smell, and Oro-mucosal safety) for Temozolomide powder for oral suspension 20mg/ml (300 mg /15ml) in Paediatric patients with Malignant Gliomas along with palatability study protocol before the committee. The firm has informed that proposed formulation is not yet approved in India

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			and anywhere in the world. The firm has informed that they have already conducted comparative bioavailability study for Temozolomide powder for oral suspension 20mg/ml (300 mg /15ml) with TEMODAL® (Temozolomide) capsules 250mg and found meets the bioequivalence criteria. Firm also informed that they have applied only for conduct of palatability study in limited numbers 14 Paediatric patient between 3 to <18 years. After detailed deliberation, the committee recommended to conduct of palatability study for Temozolomide powder for oral suspension 20mg/ml (300 mg /15ml) as per protocol presented by the firm. Further, one of the expert Dr. Sameer Bakshi (AIIMS, Delhi) is not participated in the deliberation due to conflict of interest.