Recommendations of the SEC (Oncology) made in its 18th/24 meeting held on 10.09.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/19/23 Online Submission (34512) Gedatolisib LyophilizedPowder for Infusion	M/s. PSI CRO Pharma Pvt. Ltd.	The firm presented protocol amendment version 7.1 dated 20 June 2024 protocol no. CELC-G-301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/4/24 Online Submission (34530) Savolitinib	M/s. Fortrea Development India Private Limited	The firm didn't turn up for presentation.
3.	CT/127/23 Online Submission (34528) Camizestrant	M/s. Fortrea Development India Private Limited	The firm presented protocol amendment version 3.0 dated 20 May 2024 protocol no. D8535C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/138/23 Online Submission (34540) Luspatercept (ACE-536)	M/s. Bristol-Myers Squibb India Pvt. Ltd	The firm presented protocol amendment 03 dated 29 May 2024 protocol no. CA056-025 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
5.	CT/57/21 Online Submission (34587) PF-07263896 (Encorafenib)	M/s. Pfizer Limited	The firm presented protocol amendment 6, dated 13 March 2024 and protocol amendment 7, dated 31 May 2024 protocol no. C4221015. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
6.	SND/IMP/24/000046 Pegylated liposomal irinotecan 4.3 mg/ml concentrate for dispersion for infusion	M/s. Servier India Private Limited	The firm presented their proposal for grant of permission to import and marketing of Pegylated Liposomal Irinotecan 4.3 mg/ml Concentrate for Dispersion for infusion for the additional indication of First-line treatment of adult patients with metastatic adenocarcinoma of the pancreas, in combination with oxaliplatin, 5 fluorouracil (5 FU) and leucovorin (LV) along with justification

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			for waiver of Phase-III clinical trial before the Committee. The committee noted that the alternative treatment options available for first line treatment of metastatic adenocarcinoma of the pancreas and firm has not included the Indian patients in the global clinical trial carried out for the said drug for proposed indication. After detailed deliberation, the Committee did not agree with the justification submitted by the firm for waiver of Phase-III clinical trial and recommended that firm should conduct Phase-III clinical trial in India.
7.	SND/IMP/24/000038 Olaparib film-coated Tablets 100mg and 150mg for additional indication	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for import & marketing of the drug Olaparib film-coated Tablets 100mg/150mg for additional indication as "Olaparib in combination with Durvalumab is indicated for the maintenance treatment of adult patients with advanced or recurrent endometrial cancer whose disease has not progressed on first-line treatment with Durvalumab in combination with platinum based chemotherapy" along with Global clinical trial (Phase III) data including subjects from India before the committee. The committee was apprised that the Olaparib film coated tablet 100mg & 150mg is approved in EU for the proposed indication on 14th Aug, 2024. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Olaparib film coated tablet 100mg & 150mg (Additional Indication) with waiver of Phase-III clinical trial subject to condition that the firm should conduct post marketing trial (Phase IV) study. Accordingly, the firm should submit post marketing trial (Phase IV) study protocol to CDSCO within 03 months from date of approval of the drug for further review by the SEC Committee.
New Drugs Division			
8.	ND/IMP/20/000086 Selumetinib Capsules 10 mg & 25 mg	M/s. AstraZeneca Pharma India Ltd.	Firm presented their proposal for Expansion of warning statement mentioned under condition no. 4of

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	[Koselugo]		Import and marketing permission (In Form CT-20) from "To be sold by retail on the prescription of a Oncologist/Neurologist only" to "To be sold by retail on the prescription of a Specialist only" alongwith update of Prescribing Information. After detailed deliberation, the committee did not recommend the expansion of present warning statement as proposed by the firm. However, the committee recommended for expansion of warning statement as follow: "To be sold by retail on the prescription of a Medical or Paediatric Oncologist/ Neurologist/Dermatologist/ Paediatrician/ Expert in Internal MedicineTreating neurofibromatosis type 1 (NF1) only." Further, committee recommended for update of Prescribing Information as proposed by the firm.
9.	12-01/23-DC(Pt-86) Goserelin Acetate Depot Injection 10.8mg (Zoladex)	M/s. AstraZeneca Pharma India Ltd.	Firm presented their proposal for update of warning statement mentioned under condition no. 4 of Import and marketing permission (In Form 45) for product Goserelin Acetate Depot Injection 10.8mg (Zoladex) from ''Warning- To be sold by retail on the prescription of Oncologist only'' to ''Warning- To be sold by retail on the prescription of Oncologist/Urologist only" alongwith update in India specific prescribing information. After detailed deliberation, the committee recommend for grant of approval of update in warning statement and India specific prescribing information.
10.	ND/CT/20/000022 Alpelisib film coated tablets 50mg, 150mg, 200mg	M/s. Sandoz Private Ltd.	Firm presented their proposal for reduction in sample size for an already approved Phase IV Clinical Trial with protocol no. CBYL719CIN01 of drug Alpelisib.

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			The committee noted the justification and rational presented by the firm. After detailed deliberation, the committee recommend for grant of approval for reduction in sample size of Phase IV Clinical Trial Study (CBYL719CIN01) as proposed by firm.