Recommendations of the SEC (Oncology) made in its 06th/25 meeting held on 11.02.2025. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/03/25 Online Submission (47050) KSHN001034 Injection 113 mg/mL (Eq. to 100mg Fulvestrant)	M/s Shivanka Research Private Limited	The firm presented phase 1 clinical study protocol no.: CE-24-06 version no. 3.0 dated 06-JAN-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/123/24 Online Submission (45756) OX-4224 (Evixapodlin)	M/s Klinera Global Services	In light of earlier SEC recommendation on 16.01.2025, now the firm presented phase 2 clinical study protocol no. OX-4224-200 amendment 2 dated 05 /Feb/2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
3.	E-63896 Ipilimumab injection 50mg/10mL and Nivolumab 10mg/mL concentrate for solution for infusion	M/s. BMS India Private Limited	The firm did not turn up for the presentation
4.	E-64796 Durvalumab Solution for infusion 120mg/2.4mL and 500mg/10mL	M/s. Astra Zeneca Pharma India Limited	The firm presented the proposal for update in Package Insert Version 11 of the drug product Durvalumab Solution for infusion 120mg/2.4mL and 500mg/10mL to include safety and efficacy updates in sections of posology and method of administration, special warning and special precautions for use, undesirable effects, pharmacodynamics /pharmacokinetic properties and nature and content of containers based on updates in CCDS versions. After detailed deliberation, the committee recommended for approval of updated package insert Version 11 for the proposed changes.
SND Division			
5.	SND-12013/8/2024-e-office	M/s.Novartis Healthcare private	The firm presented the proposal for update version of prescribing information

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Trametinib Tablets 0.5mg & 2 mg	limited	dated 26.08.2024 w.r.t. the changes in Clinical trials experience. After detailed deliberation, the Committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm.
6.	SND/MA/23/000061 Methotrexate Oral Solution 2mg/mL	M/s.Beta Drugs Ltd	In light of earlier SEC recommendation dated 03.04.2024 and 04.04.2024, the firm has presented the global approval status and clinical data before the committee After detailed deliberation, the committee noted that firm has conducted the BE Study in fasting state, however as per the available literature it is observed that food has been shown to delay absorption and reduce peak concentration. Hence, Committee opined that firm should conduct BE study in fed state to for further consideration. Accordingly, firm should submit BE study protocol in fed state to CDSCO for further review by the committee.
New Drug Division			
7.	12-05/2014-DC Enzalutamide 40 mg soft capsule	M/s. Astellas Pharma India Pvt. Ltd.	The firm did not turn up for the presentation.
8.	ND/IMP/24/000077 Lazertinib Film Coated tablet 80 mg and 240 mg	M/s Johnson & Johnson Pvt. Ltd	The firm presented the proposal for grant of permission for Import and Marketing of the drug Lazertinib Film Coated tablet 80 mg and 240 mg along with justification for the waiver of local Phase-III and Phase-IV clinical trial before the committee. The firm has presented the interim study report of the global Clinical Trial data for safety and efficacy of drug. After detailed deliberation, the committee recommended that firm should submit complete Phase III Clinical Study Report for further review by the committee. Further, the committee didn't agree for the waiver of Phase IV Clinical Trial.