Recommendations of the SEC (Oncology) made in its 10th/25 meeting held on 26.03.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/59/22 Online Submission (37659) CERALASERTIB (AZD6738) and DURVALUMAB (MEDI4736)	M/s PAREXEL International Clinical Research Private Limited	The firm presented protocol amendment 2.0 Version 3.0 dated 02 Dec 2024 protocol no. D533BC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/17/25 Online Submission (47925) Rilvegostomig(AZD2936) And Trastuzumab deruxtecan (T-DXd; DS-8201a)	M/s AstraZeneca Pharma India Limited	The firm presented phase III clinical study Protocol no. D702AC00001, Version 2.0 dated 02 Dec 2024 and CSP Addendum IND-2 version 2.0 dated 02 Jan 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr, Kaushal Kalra didn't participate.
3.	CT/36/22 Online Submission (37746) Selpercatinib	M/s Eli Lilly And Company	The Firm did't turn up for the Presentation.
New Drugs Division			
4.	12-34/13-DC Regorafenib tablet 40 mg	Bayer Pharmaceuticals Pvt. Ltd.	The firm presented Phase IV clinical trial report of Regorafenib Tablet 40 mg (CSR-B003376), before the committee. After detailed deliberation, the committee considered the result of the Phase IV clinical study.
SND Division			
5.	SND/MA/25/000001 Acalabrutinib Tablets 100 mg	M/s. Astrazeneca Pharma India Limited	The Firm did't turn up for the Presentation.
6.	SND/IMP/24/000110 Asciminib film-coated	M/s Novartis Healthcare Private	The firm presented the proposal for grant of permission to import and marketing of

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	20 mg and 40 mg tablets (Additional indication)	Limited	Asciminib film-coated 20 mg and 40 mg tablets with additional indication (for the treatment of adult patients with: • Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP). • Previously treated Ph+CML in CP. • Ph+ CML in CP with the T315I mutation along with global clinical trial data including Indian subjects and justification for clinical trial waiver before the Committee. The firm has informed that they are already holding MA permission for Asciminib film-coated 20 mg and 40 mg tablets which is approved on 20.10.2023 indicated for the treatment of adult patients with: • Philadelphia Chromosome-Positive Chronic Myeloid Leukemia (Ph+ CML) In Chronic Phase (CP), Previously treated with two or more tyrosine kinase inhibitors (TKIs) • Ph+ CML In CP With The T315I Mutation. Further, the firm has informed that Asciminib is approved in US, Switzerland for proposed indication. After detailed deliberation, the Committee recommended for grant of permission for import and marketing of Asciminib film-coated 20 mg and 40 mg tablets for proposed indication with CT waiver.
7.	SND/16011(11)/20/2025-e-office Dabrafenib capsules 50 mg and 75 mg	M/s. Novartis Healthcare Private Limited	The firm presented the proposal for update in the prescribing information essentially to reflect the most recent medical information on the product i.e Clinical trial experiences for adverse reactions (in the section 6.1) before the committee. The firm has informed that the update of Clinical trial experiences for adverse

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			reactions in the prescribing information is already approved by the USFDA on 11.07.2024. After detailed deliberation, the Committee recommended for grant of approval for the proposed update in the prescribing information as presented by the firm.
8.	SND/CT/24/000098 Paclitaxel Lipid suspension for injection 60 mg and 100mg	M/s Intas Pharmaceuticals Limited	The firm presented the proposal to conduct the Phase III clinical trial of Paclitaxel Lipid suspension for injection 60 mg and 100mg along with Phase III clinical protocol (Protocol no. 0127-23, ver. 6.0, dated 19th Oct-2024) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial as per protocol presented by the firm.
9.	SND/MA/24/000163 Eflornithine Hydrochloride Powder for oral suspension 0.5 g and 1.0 g	M/s Rusan Pharma Ltd.	The firm presented the proposal for grant of permission to manufactur market of Eflornithine Hydrochloride Powder for oral suspension 0.5 g and 1.0 g in proposed indication "to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy" along with published clinical data and justification for clinical trial and bioequivalence waiver before the Committee. After detailed deliberation, the committee did not recommend the CT waiver. The Committee opined that the firm should conduct Phase II clinical trial to prove the efficacy of the applied product. Accordingly, the firm should submit Phase II protocol to CDSCO for further review by the Committee.