Recommendations of the SEC (Oncology) made in its 07th/25 meeting held on 20.02.2025. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/05/25 Online Submission (47379) CT-P44 (Daratumumab)	M/s IQVIA RDS (India) Private Limited	The firm presented phase 1/3 clinical study protocol no.: CT-P44 3.1 version no. 1.0 dated 21-OCT-2024. After detailed deliberation, the committee opined that the firm should conduct bioequivalence study or present safety data for further review of the committee.
2.	CT/53/24 Online Submission (42731) FYB206 (Pembrolizumab)	M/s Syneos Health India Private Limited	The firm didn't turn up for presentation.
3.	CT/113/23 Online Submission (37352) Iberdomide	M/s PPD Pharmaceutical Development India Private Limited	The firm presented protocol amendment 4.0 dated 18 June 2024 and protocol amendment 5.0 dated 06 November 2024 protocol no. CC-220-MM-002. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/08/25 Online Submission (47443) Naxitamab and Sargramostim	M/s Novotech Clinical Research India Private Limited	The firm presented phase 2 clinical study protocol no. 201 Local Indian Protocol version 1.0dated 29 Nov2024 based on Global Protocol Version 16.0. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the number of minimum sites shall be increased up to 4.
5.	CT/48/24 Online Submission (37351) MK-2870	M/s MSD Pharmaceuticals Private Limited	The firm presented protocol amendment 01 dated 17-Sep-2024and protocol amendment 02 dated 09-Dec-2024 protocol no. MK-2870-009. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. Dr. Kaushal Kalra did not participate in the deliberation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
6.	BIO/CT04/FF/2023/40827 Polatuzumab Vedotin 140 mg & 30 mg/vial	M/s Roche Products (India) Private Limited	In light of earlier SEC recommendation dated 07.02.2025, the firm presented the revised protocol to conduct Phase IV clinical trial titled "A Phase IV, open label, study evaluating the safety and efficacy of polatuzumabvedotin in combination with Rituximab and CHP(R-CHP) in previously untreated adult patients with diffuse large B-Cell Lymphoma (DLBCL)" vide Protocol No ML45360, version 2 dated 02.05.2024. After detailed deliberation, the committee recommended to conduct the Phase IV study as per revised protocol Protocol No ML45360, version 2 dated 02.05.2024 presented by the firm. Note: Dr. Kaushal Kalra did not participate in the deliberation.
SND Division			
7.	SND/IMP/24/000088 Acalabrutinib Pharma limited	M/s Astrazeneca Pharma Limited	Firm did not participate in the meeting.