

Recommendations of the SEC (Oncology) made in its 19th/25 meeting held on 05.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/34/25 Online Submission (48701) AAA817 - [225Ac]Ac-PSMA-617	M/s Novartis Healthcare Private Limited	The firm presented phase III clinical study protocol no.: CAAA817B12301 version no. 00 dated 17-JAN-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/83/22 Online Submission (37823) BCD-201	M/s IR Innovate Research Private Limited	The firm didn't turn up for presentation.
Biological Division			
3.	BIO/CT18/FF/2024/46779 Daratumumab Solution for Injection 1800 mg	M/s. Johnson and Johnson Private Limited	The firm did not turn up for the presentation.
4.	E-82134 Thyrotropin Alfa lyophilized powder for solution for injection 0.9mg/mL (Thyrogen)	M/s. Sanofi Healthcare India Pvt Ltd	The firm presented the proposal for amendment in the warning statement of the drug Thyrotropin Alfa lyophilized powder for solution for injection 0.9mg/mL (Thyrogen®) from "To be sold by retail on the prescription of a Registered Oncologist only" to "Not to be sold by retail without the prescription of a Registered medical Practitioner". The committee noted that the drug is approved for the indication of Thyroid cancer. After detailed deliberation, the committee did not consider firm's request for the proposed amendment in warning statement.
Medical Devices Division			
5.	CI/MD/2024/134364 Hemopurifier	Qualtran Consulting	The firm presented proposal for grant of permission to conduct Pilot Clinical Investigation on proposed medical device Hemopurifier in the country on Indian

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>population before the committee.</p> <p>After detailed deliberation the committee recommended for the grant of permission to conduct of Pilot Clinical Investigation to prove safety and feasibility of the device in removing circulating exosomes of individuals with solid malignancies on Indian Population as per Study Protocol no. AEMD-2024-01-Oncology-India dated 24.05.2024</p>
SND Division			
6.	<p>SND-16011(11)/54/2025-eoffice</p> <p>Olaparib Tablets 100 mg and 150 mg</p>	M/s AstraZeneca Pharma India Limited	<p>The firm presented the proposal for update of prescribing information based on the Company Core Data Sheet of Olaparib Tablets 100 mg and 150 with respect to the changes in Special warnings and special precautions for use, Undesirable effects, Pharmacodynamic properties and Patient Information Leaflet.</p> <p>After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm.</p>
New Drugs Division			
7.	<p>ND/CT/25/000017</p> <p>Pyrotinib Maleate tablets 80mg</p>	M/s Dr Reddys Laboratories Limited	<p>The firm presented Phase III clinical trial protocol of Pyrotinib Maleate tablets 80 mg titled “A phase III, multicentre, randomized, open label, active controlled, parallel group, non-inferiority study of Pyrotinib plus Capecitabine compared with Lapatinib plus Capecitabine in patients with HER2-positive metastatic breast cancer” before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial study.</p> <p>Accordingly, firm should submit Phase III CT report to CDSCO for further review by the committee.</p>
8.	<p>ND/IMP/25/000029</p> <p>Sotorasib tablet 240</p>	M/s Amgen Technology Pvt. Ltd	The firm didn't turn up for presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	mg		