

Recommendations of the SEC (Oncology) made in its 28th/25 meeting held on 09.09.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/94/25 Online Submission (50727) PF-07248144	M/s Pfizer Limited	The firm presented phase III clinical study C4551002, Original Protocol dated 07 April 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 in the discussion.
2.	CT/127/24 Online Submission (40479) Eftilagimod alfa	M/s Fortrea Development India Private Limited	The firm presented protocol amendment version 2.0 dated 03 June 2025 protocol no. TACTI-004. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. Dr. Kalyan Kusum Mukherjee didn't participate in the discussion.
3.	CT/136/24 Online Submission (40569) Datopotamab Deruxtecan (DS-1062a) Osimertinib (AZD929)	M/s AstraZeneca Pharma India Limited	The firm presented protocol amendment version 2.0 dated 22 April 2025 protocol no. D516NC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/67/24 Online Submission (40546) Dostarlimab, Belrestotug	M/s GSK Pharma India Private Limited	The firm presented protocol amendment 3 dated 23 June 2025 protocol no. 213823. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by

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			the firm.
5.	CT/40/21 Online Submission (40595) PF-06944076 (Talazoparib) or PF-06944076 Placebo	M/s Pfizer Limited	The firm presented protocol amendment 3.0 dated 17 June 2025 protocol no. C3441052. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
6.	CT/42/24 Online Submission (40703) Zanidatamab (ZW25 and JZP598)	M/s PPD Pharmaceutical Development India Private Limited	The firm presented for Increase the number of subjects from India 13 to 41 (28 additional subjects) protocol no. JZP598-302. After detailed deliberation, the committee recommended for approval for Increase the number of subjects from 13 to 41 as presented by the firm.
Medical Devices Division			
7.	MED-14/15/2025-eoffice Cancer Diagnostic Probe	M/s. Coosa Technologies Pvt. Ltd.	The firm presented their proposal seeking No Objection Certificate (NOC) for using indigenously developed device i.e. Cancer Diagnostic Probe instead of innovator device manufactured by M/s. Nano Hesgar Sazan Salamat Arya, Tehran, Iran in the already approved Clinical study protocol, # AIIMSA2299, version 1.0 dated 15.08.2024, by this office. During the presentation, firm has informed that they have developed the device indigenously through Technology transfer from the said innovator product which is similar to the innovator device. They have compared their device with the innovator device with respect to the technical aspects.

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			After detailed deliberation, the expert committee recommended for the use of said indigenous device manufactured by the applicant for carrying out said clinical investigation (pilot study) in the Indian population.
Biological Division			
8.	BIO/CT18/FF/2025/5052 Pembrolizumab Injection 100 mg/4 ml	M/s. MSD Pharmaceutical Private Limited	<p>The firm presented the proposal for grant of approval of following additional indications of the drug Pembrolizumab Injection 100 mg/mL based on the safety and efficacy data generated from global clinical trials in these indications along with the request of local clinical trial waiver.</p> <p>i. KEYTRUDA® (pembrolizumab) in combination with chemoradiotherapy (external beam radiation therapy followed by brachytherapy), is indicated for the treatment of FIGO 2014 Stage III - IVA locally advanced cervical cancer in adults who have not received prior definitive therapy.</p> <p>ii. KEYTRUDA® (pembrolizumab), in combination with fluoropyrimidine and platinum - containing chemotherapy, is indicated for the first-line treatment of locally advanced unresectable or metastatic HER2- negative gastric or gastro-oesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS\geq1.</p> <p>iii. KEYTRUDA® (pembrolizumab), in combination with gemcitabine and cisplatin, is indicated for the</p>

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			<p>first-line treatment of locally advanced unresectable or metastatic biliary tract carcinoma in adults.</p> <p>The committee noted that the proposed indications are approved in major countries including USA, EU, UK, Japan and Australia. The committee further noted that there is no clinical data available in Indian patients for these indications however; firm has generated safety data in Phase IV study conducted in India in other indication.</p> <p>After detailed deliberation, the committee recommended for approval of the proposed additional indications with a condition to conduct Phase IV study in India in these indications.</p> <p>Accordingly, the firm should submit Phase IV study protocol within three months of approval of additional indication.</p>