Recommendations of the SEC (Oncology) made in its 22th/25 meeting held on 08.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/56/25 Online Submission (49569) PYX-201 Solution for Injection /Infusion, 100 mg/ 6.67 mL (15 mg/mL)	M/s Eteraflex Connects	The firm presented phase I clinical study Protocol no.: PYX-201-101 version no. 8.1 dated 29-APR-2025. After detailed deliberation, the committee opined that the firm shall submit the following: 1. More elaborating Preclinical safety profile data. 2. Dose ranging data for monotherapy for further review by the committee.
2.	CT/55/25 Online Submission (49573) PYX-201 Solution for Injection /Infusion, 100 mg/ 6.67 mL (15 mg/mL)	M/s Eteraflex Connects	The firm presented phase I/II clinical study Protocol no.: PYX-201-102 version no. 3.0 dated 21-APR-2025. After detailed deliberation, the committee opined that the firm shall submit the following: 1. More elaborating Preclinical safety profile data. 2. Dose ranging data for combination therapy for further review by the committee.
Biological Division			
3.	E-56365 Durvalumab Solution for Infusion 120 mg/ 2.4 ml & 500 mg/10 ml	M/s. Astra Zeneca Pharma India Ltd	The proposal was deferred as the updates proposed in the PI Version 13 was part of PI version 11 which was deliberated and approved in SEC meeting dated 11.02.2025.
4.	E-67751 Durvalumab Solution for Infusion 120 mg/ 2.4 ml & 500 mg/10 ml	M/s. Astra Zeneca Pharma India Ltd	The firm presented the proposal to conduct PMS study titled “A Prospective, observational, multicenter, post marketing surveillance study to assess safety of durvalumab in Indian adult patients with resectable Non-Small Cell Lung Cancer (NSCLC)” vide Study code no. D9106R00007, Version 1.0 Dated 22 Dec 2024.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the committee recommended for approval to conduct the PMS study as per protocol presented by the firm.
5.	BIO/CT18/FF/2024/45367 Datopotamab Deruxtecan Powder for Concentrate for Solution for Infusion 100 mg	M/s AstraZeneca Pharma India Limited	The firm presented the proposal to import and market Datopotamab Deruxtecan Powder for Concentrate for Solution for Infusion 100 mg indicated "for the treatment of adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease" based on the results of global clinical trial conducted by the firm including Indian population. The committee noted that the drug is approved in USA, EU, Japan, Australia, Singapore and other countries. After detailed deliberation, the committee recommended for grant of marketing authorization to the firm for Datopotamab Deruxtecan Powder for Concentrate for Solution for Infusion 100 mg for the said indication in line with USPI subject to the condition that the firm should conduct Phase IV clinical trial in the country. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of marketing approval.
BA/BE Division			
6.	BABE/CT05/FF/2025/47401 Lenalidomide TDS 8% -LLD-TDS-009 patch (50 cm^2 with 81 cm^2 overlay)	M/s Raptim Research Pvt. Ltd.	The firm presented the BA/BE study Protocol (For Export purpose only) No. PR/BE/24/370 Version No. 00 Protocol Date 15-JAN-2025 before the committee. After detailed deliberation, the committee

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			opined that firm should submit safety data of low strength Lenalidomide TDS 5% using Derma Roller technology before initiating higher strength Lenalidomide TDS 8% using Derma Roller technology in healthy human subjects. Accordingly, the firm should submit above data for further review by the committee.
New Drugs Division			
7.	ND/IMP/25/000029 Sotorasib tablet 240 mg	M/s Amgen Technology Pvt. Ltd	Under Discussion.
8.	ND/CT/25/000031 Brigatinib Tablet 30 mg, 90 mg, 180 mg	M/s Takeda Biopharmaceuticals Ltd.	Under Discussion.