Recommendations of the SEC (Oncology) made in its 26th/25 meeting held on 20.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/90/25 Online Submission (50479) Saruparib (AZD5305)	M/s PAREXEL International Clinical Research Private Limited	The firm presented phase III clinical study protocol no. D9727C00001 version no. 2.0 dated 10 April 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/87/25 Online Submission (50361) Trastuzumab Deruxtecan	M/s IQVIA RDS (India) Private Limited	The firm presented phase III clinical study protocol no. DS8201-793 version no. 1.0 dated 02 Dec 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/56/25 Online Submission (49569) PYX-201 Solution for Injection /Infusion, 100 mg/6.67 mL (15 mg/mL)	M/s Eteraflex Connects	In light of earlier SEC Recommendation dated 08.07.2025. The firm presented more elaborating Preclinical safety profile data and dose ranging data for monotherapy for phase I clinical study protocol no. PYX-201-101 version no. 8.1 dated 29 April 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition : 1. DSMB (country specific) shall be organized to closely monitor the safety related issues and quarterly report to the Ethics Committee and CDSCO. 2. The PI/Co-PI shall be Medical-Oncologist/ Pharmacologist.
4.	CT/55/25 Online Submission (49573) PYX-201 Solution for Injection /Infusion, 100 mg/6.67 mL (15 mg/mL)	M/s Eteraflex Connects	In light of earlier SEC Recommendation dated 08.07.2025. The firm presented more elaborating Preclinical safety profile data and dose ranging data for monotherapy for phase I/II clinical study protocol no. PYX-201-102 version no. 3.0 dated 21 April 2025. After detailed deliberation, the committee recommended for grant of permission to

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			conduct the trial as presented by the firm with following condition : 1. DSMB (country specific) shall be organized to closely monitor the safety related issues and quarterly report to the Ethics Committee and CDSCO. 2. The PI/Co-PI shall be Medical-Oncologist/ Pharmacologist.
5.	CT/22/25 Online Submission (40801) PF-08046047 - SGN B6A-Sigvotatug Vedotin	M/s Pfizer Limited	The firm presented protocol amendment 3.0 dated 20 May 2025 protocol no.C5751003. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
6.	BIO/CT18/FF/2025/50150 Nivolumab 10 mg/ml concentrate of solution for infusion (40mg/4ml, 100mg/10ml and 240mg/24ml)	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm did not turn up for the presentation.
7.	BIO/CT04/FF/2025/49618 Denosumab Injection 120mg/0.7ml.	M/s Hetero Biopharma Limited	The firm presented the proposal for grant of permission to conduct Phase IV clinical trial titled "A Phase IV Multi-Centric, Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero-Denosumab in patients with Advanced Malignancies involving Bone or Giant Cell Tumour of Bone" vide Protocol No. HCR/IV/ DENOSOL/01/2025 Version 1.0 dt. 18 Mar 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the protocol presented by the firm. **Note:** Dr. Kaushal Kalra did not participate in the deliberation.
8.	BIO/CT04/FF/2025/49604	M/s Jeevan Scientific Technology	The firm presented the proposal for grant of permission to conduct Phase I clinical trial titled "A phase 1, double-blind,

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	Bevacizumab Injection 400mg/16mL	Limited	balanced, randomized, two-treatment, two-arm, single-period, single-dose, parallel, comparative pharmacokinetic study of BE1040Vinjection 400mg/ 16ml of AryoGen Pharmed., Iran comparing with Avastin 400mg/ 16ml concentrate for solution for infusion of Roche Registration GmbH Emil-Barell-Strasse1 79639 Grenzach-Wyhlen Germanyin normal, healthy, adult, human subjects under fasting condition."; vide Protocol No.: 25-025, Version No. 01 date: 10 Apr 2025 for export purpose. The firm also presented data from the Phase III clinical study conducted in Iran, including safety data. The committee noted that the drug product is approved in the country of origin. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per the protocol presented by the firm.
SND Division			
9.	SND/MA/25/000128 Mercaptopurine Oral Suspension BP 20 mg/ml	Zydus Lifesciences Limited	Under Discussion.
10.	SND/MA/24/000086 Enzalutamide tablets 40 mg, 80 mg and 160 mg	M/s. Sun Pharmaceutical Industries Limited	Firm presented their proposal for grant of permission to manufacture and market Enzalutamide Tablets 40 mg, 80 mg and 160 mg for the treatment of adult men with metastatic castration-resistant prostate cancer who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated and adults with metastatic castration-resistant prostate cancer (mCRPC) whose disease has progressed on or after docetaxel therapy along with BE study report of Enzalutamide Tablets 160 mg before the committee. The committee noted that Enzalutamide

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			Tablets 40 mg and 80 mg are approved by USFDA/EMA for applied indication. Enzalutamide Tablets 160 mg is also approved in India since 2022 and firm has performed BE study using approved Enzalutamide Tablets 160 mg as comparator. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Enzalutamide Tablets 40 mg, 80 mg and 160 mg for the applied indication.