Recommendations of the SEC (Oncology) made in its 31st/25 meeting held on 09.10.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/119/25 Online Submission (51536) JPB898 (Nivolumab) 10 mg/ml (240 mg/24 ml) Concentrate for solution for infusion	M/s. Veeda Clinical Research Limited	The firm presented phase I clinical study Protocol no. CJPB898A12101 version no. 2.0 dated 29-JUL- 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following conditions: 1. Immunogenicity assessment shall be performed at every 2, 4, 8 & 16 weeks of treatment cycles apart from the pre-dose assessment. 2. Participants must be followed for safety for at least 180 days after last dose of study intervention.
2.	CT/127/25 Online Submission (51609) Inotuzumab Ozogamicin	M/s. Pfizer Limited	The firm presented phase II clinical study Protocol no. B1931036 Amendment 3 dated 20 Sep 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
3.	BIO/CT21/BO/2025/49420 Lyophilized Recombinant L-Asparaginase-II bulk & Injection 10000 IU	M/s. Gennova Biopharmaceuticals Limited	The firm did not turn up for the presentation.
4.	BIO/CT18/FF/2024/46779 Daratumumab Solution for Injection 1800 mg- in combination with bortezomib, lenalidomide and dexamethasone	M/s. Johnson & Johnson Pvt. Ltd.	The firm presented the proposal for grant of approval of additional indication: "Daratumumab in combination with bortezomib, lenalidomide and dexamethasone for the treatment of adult patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant" aligned with EMA approval along with a request for a local clinical trial waiver. The committee noted that the drug Daratumumab 1800 mg (120 mg/mL) (r-DNA origin) for subcutaneous Injection is approved in India since June 2021 and the proposed indication is approved in 47

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			countries including US, EU, Japan, Australia and Canada. After detailed deliberation, the committee recommended for grant of approval for the proposed additional indication.
BABE Division			
5.	BABE/CT05/FF/2025/ 50031 Degarelix Extended-Release Injection, 371 mg/mL	M/s. CBCC Global Research LLP	The firm presented the Study Protocol No. TOL3022A-101, Version No. 02, Protocol Date- 29-08-2025 for export purpose only. After detailed deliberation, the committee recommended for grants of permission for conduct of the Bioavailability study for export purpose only.
New Drugs Division			
6.	ND/IMP/25/000001 Inavolisib film-coated tablets 3 mg and 9 mg (Itovebi)	M/s. Roche Products (India) Private Limited	The firm presented the proposal for grant of permission for Import and Marketing of the drug Inavolisib film-coated tablets 3 mg and 9 mg (Itovebi) mg along with justification for local Phase III Clinical Trial waiver before the committee and request to conduct PMS. The firm also presented efficacy data of international pivotal Phase III study & details of ongoing Phase III global clinical trial with participation of Indian subjects. The committee noted that the drug is approved in US, EU, Canada, Australia, and Switzerland. The committee also noted that there is unmet medical need in the country. The committee reviewed the Indian Package insert and noticed that the side effects & dose adjustments mentioned in the international PI are not captured in Indian PI. The committee reviewed and recommended that the product need to be studied in structured phase IV trial on Indian patients considering the side the effects profile of product. After detailed deliberation, the committee recommended for the grant of permission

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			for the import and marketing of the drug Inavolisib film-coated tablets 3 mg and 9 mg with waiver of Phase III clinical trial with the condition that the firm should conduct Phase IV clinical trial for which the protocol should be submitted within 3 months of approval of the drug for review by the committee. Further, committee recommended that the firm should submit revised PI to CDSCO for review before grant of MA.
SND Division			
7.	SND/CT/25/ 000089 Capecitabine Tablets BP 500 mg	M/s. Synergen Bio Pvt. Ltd	The firm did not turn up for the presentation.
8.	SND/CT/25/000092 SND/CT04/FF/2025/51289 Ondansetron Extended Release injectable Suspension 100 mg/ml	M/s. Shilpa Medicare Limited	The firm submitted the Phase III clinical trial proposal for the grant of application for manufacturing and marketing of the applied product Ondansetron Extended Release Injectable Suspension 100 mg/ml. After detailed deliberation, the committee opined that additional information for rationality of applied dosage form in respect to dose calculation with respect to oral dose should be submitted. The Committee also recommended that firm has to submit more data of the ongoing Phase III clinical trial of applied product dosage form.
9.	SND/IMP/20/000072 Osimertinib Tablets 40 mg & 80 mg	M/s. AstraZeneca Pharma India Limited	In light of earlier SEC recommendations dated 06.05.2025, the firm presented subset PV data on Indian patients w.r.t. the skin hyper pigmentation adverse reaction by Osimertinib Tablets 40 mg and 80 mg before the committee. After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information of Osimertinib Tablets 40 mg and 80 mg as presented by the firm.