Recommendations of the SEC (Oncology) made in its 15th/25 meeting held on 06.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2024/46780 Durvalumab Solution for Infusion 120 mg/ 2.4 ml & 500 mg/ 10 ml	M/s. AstraZeneca Pharma India Limited	The firm presented the proposal for the approval of additional indication of the drug product Durvalumab solution for infusion (IMFINZI)120mg/2.4mL and 500 mg/10mL i.e. Urothelial Carcinoma- "Imfinzi in combination with cisplatin-based chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy adjuvant treatment after radical cystectomy is indicated for the treatment of patients with muscle invasive bladder cancer (MIBC)" based on the results of a global clinical trial in the proposed indication along with the request for Phase III clinical trial waiver in India. The committee noted that the proposed indication is approved in USA, Australia, Brazil, Canada, Singapore and Switzerland and there is an unmet need in the country for the proposed indication. After detailed deliberation, the committee recommended for approval of proposed additional indication in line with indication approved by USFDA i.e. "Imfinzi in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent IMFINZI as adjuvant treatment following radical cystectomy, for the treatment of adult patients with muscle invasive bladder cancer (MIBC)" with the condition to conduct a Phase IV clinical trial in India in the proposed indication. Accordingly, the firm shall submit Phase IV protocol to CDSCO within 03 months of the grant of permission for additional indication
2.	BIO/CT21/BO/2024/46843 Trastuzumab 150 mg/ 440 mg (PGS formulation)	M/s. Biocon Biologics Ltd	Under Discussion.

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3.	E-63896 Ipilimumab injection 50 mg/ 10 mL and Nivolumab 10 mg/ mL concentrate for solution for infusion.	M/s. BMS India Pvt Ltd	The firm presented the final clinical study report (CSR) of Phase IV clinical trial titled "A Phase 4 Study of Nivolumab in Combination with Ipilimumab in Patients with Previously Untreated Advanced Renal Cell Carcinoma and Intermediate- or Poor-risk Factors" conducted in India as per Protocol No.: CA209-7C9, Version No. 1.0, dated 06-Feb-2020. After detailed deliberation, the committee noted the results of the Phase IV clinical trial presented by the firm
New Drugs Division			
4.	ND/IMP/25/000011 Lutetium Lu 177 vipivotide tetraxetan solution for injection or infusion 1000 MBq/mL	M/s Novartis Healthcare Private Limited	The firm presented the proposal for grant of permission to import and market of new drug Lutetium Lu 177 Vipivotide tetraxetan solution for injection or infusion 1000 MBq/mL with justification for Phase III and Phase IV clinical trial waiver before the committee. The committee noted that the drug is approved in 47 countries including US, EU, UK Canada, Australia etc. The firm presented the results of Phase III VISION study conducted in other countries which demonstrated significant improvements in overall survival and radiographic progression free survival for patients with progressive PSMA positive mCRPC compared to standard of care. The Subject Expert Committee including the experts from AERB and nuclear medicine speciality opined that there is an unmet medical need. After detailed deliberation, the committee recommended for grant of permission to import and market Lutetium Lu 177 vipivotide tetraxetan solution for injection or infusion 1000 MBq/mL for the proposed indications with local Phase III CT waiver subject to the condition that 1) The firm should conduct Phase IV clinical trial for which the protocol should be submitted to CDSCO within 3 months of approval of the drug for further

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			review by the committee. 2) The said imported product should be used only at AERB approved facilities.
SND Division			
5.	SND/IMP/20/000072 Osimertinib Tablets 40mg & 80mg	M/s AstraZeneca Pharma India Limit	The firm presented the proposal for update of prescribing information (Version 12 dated 16 Apr 2024) of Osimertinib Tablets 40 mg and 80 mg w.r.t. skin hyperpigmentation adverse reaction under Undesirable effects section based on global data before the committee. The committee noted that Osimertinib Tablets 40 mg and 80 mg was approved and marketed since year 2017 for various indications. After detailed deliberation, the committee opined that firm should submit subset PV data on Indian patients w.r.t. the skin hyperpigmentation adverse reaction by Osimertinib Tablets 40 mg and 80 mg for further review by the committee.
6.	SND/IMP/24/000091 Asciminib film-coated tablets 100mg	M/s Novartis Healthcare Private Limited	The firm presented the proposal for grant of permission to import and marketing of Asciminib film-coated 100 mg tablets (Additional strength) for proposed indication along with justification for clinical trial waiver before the Committee. The firm has informed that they are already holding MA permission for Asciminib film-coated 20 mg and 40 mg tablets for proposed indication in India. Further, the firm has informed that Asciminib film-coated 100 mg tablets is approved in US on dated 18-Apr-2024. After detailed deliberation, the Committee recommended for grant of permission for import and marketing of Asciminib film-coated 100 mg tablets for proposed indication with CT waiver.
7.	SND-16011(11)/ 25/ 2025- eoffice (Receipt no.58434)	M/s Astrazeneca Pharma Limited	The firm presented the proposal for update of prescribing information (CDS v.6 dated 17 th June 2021) of

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	Acalabrutinib Capsules 100 mg		Acalabrutinib Capsules 100 mg w.r.t. changes in the Posology and method of administration section of the Prescribing information. After detailed deliberation, the committee recommended for the updation of proposed changes in the Prescribing information.
8.	SND-16011(11)/54/2025-eoffice Olaparib Tablets 100 mg and 150 mg	M/s AstraZeneca Pharma India Limited	The firm did not turn up for the presentation.