Recommendations of the SEC (Oncology) made in its 03nd/26 meeting held on 28.01.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2025/52279 Durvalumab Solution for Infusion 120 mg/2.4 ml and 500 mg/10 ml.	M/s. AstraZeneca Pharma India Limited.	The firm withdrew the application from the Biological Division.
2.	BIO/CT04/FF/2025/52474 Durvalumab Solution for Infusion 120 mg/2.4 ml and 500 mg/10 ml.	M/s. AstraZeneca Pharma India Limited.	The firm presented the proposal to conduct Phase IV clinical trial titled "A Phase IV, prospective, multi-centre, single-arm safety study titled-Prospective, Multi-Center, Phase 4, Single Arm Study to Assess The Safety and tolerability of Perioperative Durvalumab in Combination with Neoadjuvant Gemcitabine Plus Cisplatin in Indian Patients with Muscle-Invasive Bladder Cancer" Study code: D933RL00001D, Version: 1.0 dated 06-Oct-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the presented protocol, subject to the following conditions: 1. All PIs shall be Medical Oncologist. 2. Day care facilities shall not be used as a clinical trial site. 3. Clinical trial sites shall be geographically distributed. **Note:** Dr. Kaushal Kalra did not participate in the deliberation.
3.	E-114243 Pertuzumab-Trastuzumab Injection 600 mg + 600 mg [10 ml/15 cc vial] and 1200 mg + 600 mg vial [15 ml/20 cc vial] [Phesgo®]	M/s. Roche Products (India) Pvt. Ltd.	The firm presented the proposal for update in the Package Insert of Pertuzumab-Trastuzumab Injection 600 mg + 600 mg (10 mL/15 cc vial) and 1200 mg + 600 mg (15 mL/20 cc vial) (Phesgo®) from Version 2.0 to Version 3.0. The proposed update included revisions to Section 1.1 Therapeutic/Pharmacologic Class of Drug; Section 2.6.1 Clinical Trials under Section 2.6 Undesirable Effects, Section 3.1.2 Clinical/Efficacy Studies – Early

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			Breast Cancer and Section 3.1.3 Immunogenicity, based on the results of the Phase III FEDERICA clinical trial and in line with the EMA-approved Package Insert. After detailed deliberation, the committee recommended approval of the updated Package Insert January 2025 Version 3.0 incorporating the proposed changes.
4.	E-116893 Polatuzumab Vedotin for Injection 30mg/vial & 140 mg/vial	M/s. Roche Products (India) Pvt. Ltd.	The firm presented the proposal for update in the Package Insert of Polatuzumab Vedotin for Injection 30 mg/vial and 140 mg/vial (Polivy®) from Version 4.0 to Version 5.0. The proposed update included safety-related revisions in Section 4.4 Special Warnings and Precautions for Use and Section 4.8.1 Clinical Trials & Section 4.8.2 Postmarketing Experience under Section 4.8 Undesirable Effects. After detailed deliberation, the committee recommended for approval of the updated Package Insert October 2025 Version 5.0, incorporating the proposed changes.
New Drug Division			
5.	ND/166/2025-eoffice Niraparib Tablets 100 mg [Zejula]	M/s. GSK	The firm presented proposal for update in Prescribing Information of drug Niraparib tablets 100 mg [Zejula] (Version: ZEJ/PI/IN/2025/01, Dated:25-Sep-2025), before the committee. After detailed deliberation, the committee recommended for update in prescribing Information, as presented by firm.
6.	ND/CT/25/000100 Ivosidenib 250 mg Film coated Tablets	M/s. Servier India Private Limited	In line with the condition of permission for import and marketing of the drug Ivosidenib 250 mg Film coated Tablets, the firm presented Phase-IV Clinical Trial protocol (Protocol no. SERV-IVO-001, Version No.: 1.0 and Date 04 Oct, 2025), before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial as presented by the firm.
7.	ND/160/2025-eoffice Lutetium Lu 177	M/s. Novartis Healthcare Private Limited	The firm presented the proposal for amendment in the warning statement from ‘To be sold on the prescription of

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	vipivotide tetraxetan solution for injection or infusion 1000 MBq/mL		Nuclear Medicine Expert only' to 'To be sold on the prescription of a Nuclear Medicine Expert or Oncologist' in the permission granted to import and market of Lutetium Lu 177 vipivotide tetraxetan solution for injection or infusion 1000 MBq/mL before the committee. After detailed deliberation, the committee recommended for the amendment in warning statement from 'To be sold on the prescription of Nuclear Medicine Expert only' to 'To be sold on the prescription of Nuclear Medicine Expert or Medical Oncologist'.
SND Division			
8.	SND/CT/25/000112 SND/CT04/FF/2025/52314 Olaparib film coated tablets 100 mg and Olaparib film coated tablets 150 mg	M/s. AstraZeneca Pharma India Limited	Firm presented proposal for grant of permission to conduct Phase IV Clinical Trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV Clinical Trial as per the protocol presented by the firm with the following conditions that: Firm shall exclude the HER2 positive patients from the study. Expert Dr. Kaushal Kalra did not participate in the deliberation.