**Recommendations of the SEC (Oncology) made in its 20th meeting held on 17.06.2025 at CDSCO HQ New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **GCT Division** | | | |
| 1. | CT/68/24<br><br>Online Submission (38984)<br><br>MK 1084 | M/s MSD Pharmaceuticals Private Limited | The firm presented protocol amendment 1 dated 17 May 2024 and protocol amendment 2 dated 04 October 2024 protocol no. 004.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 2. | CT/47/24<br><br>Online Submission (39173)<br><br>AZD0901 Powder for Solution for infusion | AstraZeneca Pharma India Limited | The firm presented protocol amendment version 3.0 dated 25 March 2025 protocol no. D9802C00001.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 3. | CT/64/25<br><br>Online Submission (49336)<br><br>Camizestrant | M/s Fortrea Development India Private Limited | The firm presented phase III clinical study protocol no. D8536C00001 version no 2.0 dated 07 March 2025.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that More geographically distributed government sites shall be included in the study. |
| 4. | CT/136/23<br>Online Submission (39199)<br><br>Datopotamab deruxtecan (DS-1062a) 100 mg/ vial<br><br>Durvalumab (MEDI4736) 500 mg/ vial | M/s AstraZeneca Pharma India Limited | The firm presented protocol amendment version 4.0 dated 22 April 2025 protocol no. D926QC00001.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 5. | CT/66/24<br><br>Online Submission (39253)<br><br>Mezigdomide (CC-92480) | M/s Bristol-Myers Squibb India Pvt. Ltd | The firm presented protocol amendment 6.0 dated 18 Feb 2025 protocol no. CA057-001.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 6. | CT/112/23<br>Online Submission (39359) | M/s. Roche Products (India) | The firm presented protocol amendment version 3.0 dated 07 |

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|---|---|---|---|
| | Inavolisib (RO7113755), Phesgo (Pertuzumab, Trastuzumab & Hyaluronidase [rHuPH20] (RO7198574) | Private Limited | March 2025 protocol no. WO44263.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 7. | CT/150/23<br><br>Online Submission (39414)<br><br>GSK4057190A/Dostarlimab | M/s GSK Pharma India Private Limited | The firm presented for Increase in number of patients sample size from India 50 to 100 protocol no. 221530.<br><br>After detailed deliberation, the committee recommended for approval of Increase in number of patients sample size from India 50 to 100 as presented by the firm. |
| **SND Division** | | | |
| 8. | SND/CT/19/000043<br><br>Lenvatinib Capsules 4 mg and 10 mg | M/s Eisai Pharmaceuticals India Private Limited | Firm presented the report of Phase IV clinical trial of the product Lenvatinib Capsules in patients with unresectable hepatocellular carcinoma (HCC).<br><br>The committee noted that, adverse events were reported during the Phase IV CT study. However, firm could not present the details and its assessment for the same.<br><br>After detailed deliberation, the committee recommended to submit the complete details of adverse events reported during the Phase IV CT study along with its assessment reports to CDSCO for further review by the committee. |