**Recommendations of the SEC (Oncology) made in its 05th/25 meeting held on 06.02.2025. at CDSCO (HQ), New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| **GCT Division** | | | |
| 1. | CT/111/22<br>Online Submission (36800)<br>Teclistamab | M/s Johnson and Johnson Pvt. Ltd. | The firm presented protocol amendment 4 dated 01 October 2024 protocol no. 64007957MMY3006.<br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 2. | CT/130/23<br>Online Submission (37022)<br><br>Volrustomig (MEDI5752) | M/s AstraZeneca Pharma India Limited | The firm presented protocol amendment 4.0 dated 03 December 2024 protocol no. D798AC00001.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 3. | CT/68/24 43277<br>Online Submission (43277)<br>MK-1084 | M/s MSD Pharmaceuticals Pvt. Ltd. | In light of earlier SEC recommendation dated 05.12.2024, the firm presented justification for the conditions of phase 3 clinical study protocol no. MK- 1084-004 version 00 dated 15 December 2023.<br>After detailed deliberation, the committee opined that the recommendation of SEC dated 05.12.2024 shall remain the same and number of sites shall be increased in the study. |
| 4. | CT/16/24<br><br>Online Submission (37214)<br>GME751 (Pembrolizumab) | M/s Parexel | The firm presented protocol amendment version 3.0 dated 07 August 2024 protocol no. CGME751A12301.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| 5. | CT/49/24<br>Online Submission (37260)<br>Acalabrutinib (ACP-196) | M/s Fortrea Development India Pvt. Ltd | The firm presented protocol amendment version 8.0 dated 07 November 2024. Protocol no. ACE-LY-312 (D8227C00001).<br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| **SND Division** | | | |
| 6. | e-receipt no. 50681/2024/CRU (C. No.50681)<br><br>Ruxolitinib Tablets 5mg, 10mg,15mg & | M/s Novartis Healthcare Private Limited | The firm did not turn up for the presentation. |

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| | 20mg | | |
| **New Drug Division** | | | |
| 7. | ND/MA/23/000080 Tucatinib Tablets 50 mg/150mg | M/s BDR Pharmaceuticals International Pvt. Ltd. | The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Tucatinib Tablets 50 mg/150mg along with justification for the waiver of Phase III clinical trial before the committee.<br>The firm presented data on prevalence of disease HER2 positive breast cancer. The committee considered the subject drug as defined in NDCT Rules 2019 as orphan drug. The committee noted that it is an orphan drug approved in other countries like USA, EU etc. The committee agreed for Phase III CT waiver.<br>After detailed deliberation, the committee recommended for the grant of permission to manufacture and market of drug Tucatinib Tablets 50 mg/150mg for the applied indication subject to the following conditions:<br>1. The drug should be sold by retail under prescription of Oncologist only.<br>2. The firm should conduct structured Phase IV clinical trial in atleast 200 patients for which the protocol should be submitted within 3 months of approval of the drug for review by the committee. |
| 8. | ND-12011(13)/4/2025-eoffice (ND/CT/20/000093)<br><br>Acalabrutinib capsules 100 mg | M/s. AstraZenica Pharma India Ltd. | The firm presented Phase IV clinical trial report of drug Acalabrutinib capsules 100 mg along with their request of discontinuation of Post-Trial Access for the study participants enrolled in the phase-IV Clinical trial of Acalabrutinib capsules 100 mg, before the committee.<br><br>After detailed deliberation, the committee considered the result of the Phase IV clinical trial study.<br><br>Further, with regard to the post trial access of drug Acalabrutinib capsules 100 mg, the committee recommended that post trial assess should be continued to the study participants till the progression of disease. |

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
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