**Recommendations of the SEC (Oncology) made in its 03rd/25 meeting held on 21.01.25 at CDSCO (HQ), New Delhi:**

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **GCT Division** | | | |
| 1. | CT/119/23<br>Online Submission (36462 )<br><br>Pembrolizumab | M/s Fortrea Development India Private Limited | The firm presented the proposal to increase the number of subjects from 86 to 111 vide approved protocol no. SB27-3004.<br>After detailed deliberation, the committee recommended for approval to increase in number of subjects from 86 to 111 as presented by the firm. |
| 2. | CT/29/24<br>Online Submission (36566 )<br>Capivasertib | M/s Fortrea Development India Private Limited | The firm presented protocol amendment version 5.0 dated 28 Oct 2024 protocol no. D361EC00001.<br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. |
| **Biological Division** | | | |
| 3. | BIO/CT18/FF/2024/45896<br><br>Trastuzumab deruxtecan concentrate solution for infusion 100 mg | M/s AstraZeneca Pharma India Limited | The firm did not turn up for the deliberation. |
| 4. | BIO/CT21/FF/2024/45637<br><br>Denosumab Injection 120mg/1.7ml in Vial | M/s Reliance Life Sciences Pvt Ltd | The firm presented the proposal for approval of additional indication for the drug product Denosumab Injection 120mg/1.7ml in Vial i.e "for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity" in line with the indication approved for the innovator product by the way of extrapolation of indication.<br>After detailed deliberation, the committee recommended for the approval of proposed additional indication. |
| **New Drugs Division** | | | |
| 5. | ND/CT/24/000085<br><br>Gilteritinib 40 mg Tablets | M/s Astellas Pharma India Pvt.Ltd | Under Discussion. |

| S. No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **BA/BE Division** | | | |
| 6. | BABE/CT05/FF/2024 /45753<br><br>Mercaptopurine tablets 50 mg. | M/s Watson Pharma Pvt. Ltd. | The firm presented BA/BE study Protocol No. BE-2388-24, Version 1.0 dated 12/SEP/24 for export purpose only.<br><br>After detailed deliberation, the committee opined that the firm should reduce the blood collection time points and total blood loss in healthy subjects as the mercaptopurine is well characterized drug. Accordingly, the firm should submit the revised protocol for further deliberation in the SEC committee. |
| **SND Division** | | | |
| 7. | SND-12012/6/2024-e-office (58437)<br><br>Goserelin Acetate 3.6mg (ZOLADEX®) | M/s Astrazeneca Pharma Limited | The firm presented the proposal for update of prescribing information based on the Company Core Data Sheet of Goserelin Acetate 3.6mg (ZOLADEX®)w.r.t. the changes in Clinical particulars,Pharmacological Properties, Pharmaceutical Particulars.<br><br>After detailed deliberation, the Committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm. |
| 8. | SND-12013/8/2024 (Computer No. 61192)<br><br>Trametinib Tablets 0.5 mg & 2 mg | M/s Novartis Healthcare Private Limited | The firm did not turn up for the presentation. |