**Recommendations of the SEC (Oncology & Haematology) made in its 142nd meeting held on 09.02.2023 at CDSCO (HQ), New Delhi:**

| S.No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **New Drug Division** | | | |
| 1. | ND/IMP/22/000063<br><br>Asciminib FCT 20mg & 40mg | M/s. Novartis Health Care Pvt. Ltd. | The firm did not turn up for presentation. |
| 2. | ND/CT/21/000090<br><br>Darolutamide Tablet 300mg | M/s. Bayers Pharmaceuticals Pvt. Ltd | The firm presented its proposal for protocol no. 21707 amendment 1, version 2.0 dated 25.10.2022 and ICF for already approved Phase IV clinical trial of Darolutamide 300mg tablet.<br><br>After detailed deliberation, the committee recommended for the approval of the protocol amendment.<br><br>Note: Dr. C.K. Bose did not participate during the deliberation. |
| 3. | ND/MA/23/000004<br><br>Ferumoxytol Injection 510mg Elemental Iron/17mL (30mg/mL) | M/s. MSN Laboratories Private Limited | The firm did not turn up for presentation. |
| 4. | ND/IMP/22/000015<br><br>Selpercatinib 40 & 80mg capsules | M/s. Eli-Lilly & Company | In light of earlier SEC recommendation dated 11.05.2022, the firm presented its proposal to waive off Phase IV clinical trial in the country, before the committee.<br><br>After detailed deliberation, the committee recommended that the firm should submit the following data:<br><br>1. The criteria of dose justification for Indian patients.<br>2. Comparative safety data of Indian and Global study particularly ICH countries who participated in the study by including all AEs and SAEs.<br>3. Reasons why out of 41 screened patients only 07 were randomized and 32 were discontinued before randomization.<br><br>Accordingly, the firm should submit above data to CDSCO for re-deliberation before the committee. |

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| **SND Division** | | | |
| 5. | SND/MA/22/000313<br><br>Micronized Purified Floavonoid Fraction 500 mg Tablet | M/s. Seriver India | In light of earlier SEC recommendation dated 10.01.2023, the firm presented the proposal of manufacture and marketing permission of Purified Flavonoid Fraction 500mg Tablets (Additional Strength) for the indication as:<br><br>1. "Treatment of symptoms related to venolymphatic insufficiency (heavy legs, pain, restless leg syndrome).<br><br>2. Treatment of functional symptoms related to hemorrhoidal attack alongwith justification of clinical trial waiver before the committee.<br><br>The committee noted that the firm had conducted one clinical trial globally in the year 2002 for the proposed indication.<br><br>After detailed deliberation, the committee recommended that the firm should submit the clinical trial data and approval status of the applied drug product in other countries with proposed indications to CDSCO for further review by the committee. |
| **FDC Division** | | | |
| 6. | FDC/MA/22/000258<br><br>Ferrous BisGlycinate +Vitamin B12 +Vitamin D3 + Folic acid (10mg + 0.8mcg + 20mcg + 100mcg) | M/s. Murali Krishna Pharma Pvt. Ltd | Inlight of earlier SEC recommendation dated 07.10.2022, the firm presented its proposal along with justification.<br><br>After detailed deliberation, the committee recommended that:<br><br>1. The firm should present preclinical study data generated as per NDCT Rules 2019.<br><br>2. The firm should present the PK study protocol.<br><br>Accordingly, the firm should present the proposal before the SEC. |

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| **GCT Division** | | | |
| 3. | CT/143/22<br>Online Submission (34837)<br><br>Ianalumab (VAY736) | M/s. Novartis | The firm did not turn up for presentation. |
| 4. | CT/111/22<br><br>OnlineSubmission (34102)<br><br>Teclistamab Versus Pomalidomide, Bortezomib | M/s. J&J | The firm presented its proposed (MajesTEC-9) clinical study protocol no. 64007957MMY3006, original version dated 14-Sep-2022 before the committee.<br><br>After detailed deliberation, the committee recommended for the conduct of the proposed study with condition that-<br><br>1) The firm and the PI/site should report all the SAEs (death due to PD) as per NDCTR 2019 to CLA/CDSCO as prescribed under NDCT Rules, 2019.<br><br>The firm should submit IDMC recommendation along with interim analysis as per the protocol to CDSCO for further review by the committee. |
| 5. | CT/32/22<br>Online Submission (22548)<br>Durbalumab+ Olaparib | M/s. Labcorp | The firm did not turn up for presentation. |
| 6. | CT/156/22<br>Online Submission (34990)<br><br>JNJ-63723282 | M/s. J&J | The firm presented its clinical trial Phase I/II protocol along with the amendment 6 (part-5) before the committee.<br><br>After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment 6- Part 5 subject to the condition that the firm and the PI/site should report all the SAEs (death due to PD) as per NDCT Rules 2019 to CLA/CDSCO as prescribed under NDCT Rules, 2019. |
| 7. | CT/54/20<br>Online Submission (21775)<br><br>Trastuzumab deruxtecan(T-DXd) | M/s. Astra Zeneca | The firm presented its proposed protocol amendment 3.0 (Version 4.0) dated 27-Apr-2022 under the DESTINY-Breast06 protocol no. D9670C00001 before the committee.<br><br>During presentation, the committee noted |

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| | | | that the global recruitment is completed. Hence, the amendment for the enrollment pause for HER2 IHC and updating to inclusion criteria 2c are not applicable at this stage.<br><br>After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendment as presented by the firm. |
| 8. | CT/118/22<br>Online Submission (34155)<br><br>Nuvastatic 1000mg | M/s. Ardent Clinical Research Service | The firm presented its proposed Phase IIb/III clinical trial protocol no. EBSB003, version 1.5 dated 02-Dec-2022 before the committee.<br><br>The firm informed that the product (Nuvastatic) is registered in Malaysia as traditional medicine, in Australia as complimentary medicine and in USA as food supplement. The firm requested for waiver of Phase I clinical trial in India before the committee.<br><br>The committee also noted that the firm presented Phase I and Phase II/III clinical trial data from India which were not approved by CDSCO, as CLA/DCGI permission was not taken. Hence, data from such non-regulatory trials could not be accepted.<br><br>After detailed deliberation, the committee did not recommend for grant of permission to conduct the proposed Phase IIb/III clinical trial and opined that initially, the applicant should conduct appropriate pre-clinical studies and Phase I clinical trial as per the provisions of New Drugs and Clinical Trial Rules, 2019 for further review by the committee. |