

**Recommendations of the SEC (Oncology & Haematology) made in its 139<sup>th</sup> meeting held on 22.12.2022 at CDSCO (HQ), New Delhi:**

| S.No.                      | File Name & Drug Name, Strength                                       | Firm Name                   | Recommendations  |
|----------------------------|---|-----------------------------|--|
| <b>Biological Division</b> |   |                             |  |
| 1.                         | BIO/MA/22/000113<br><br>Bevacizumab100 mg/ 4 mL & 400 mg/16mL in Vial | M/s Enzene Biosciences Ltd. | <p>The firm presented the proposal for manufacture and marketing of Bevacizumab100mg/ 4ml &amp; 400 mg/16ml in vial for the indication “Bevacizumab in combination with fluoropyrimidine-based chemotherapy is indicated for treatment of adult patients with metastatic carcinoma of the colon or rectum” along with the results of local Phase III clinical trial.</p> <p>The committee noted the results of the Phase III clinical trial.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the drug subject to the condition that firm should conduct Phase IV clinical trial. Accordingly, Phase IV clinical trial protocol should be submitted within 3 months of marketing approval.</p> <p>Dr. Atul Sharma did not participate in the deliberation.</p> |
| 2.                         | 4-33/Roche/PAC-R-Trastuzumab/18-BD<br><br>Trastuzumab                 | M/s Roche                   | <p>The firm presented the results of Phase IV clinical trial as per condition of permission dated 28.01.2011 for the additional indication “for adjuvant treatment of HER2 overexpressing node positive or node negative (ER/PR negative or with one high risk feature) breast cancer</p> <ul style="list-style-type: none"> <li>• As part of a treatment regimen consisting of doxorubicin, cyclophosphamide and either paclitaxel or docetaxel.</li> <li>• With docetaxel and carboplatin”.</li> </ul> <p>After detailed deliberation, the committee noted the results of the study.</p>   |
| <b>SND Division</b>        |   |                             |  |
| 3.                         | SND/MA/22/000293<br><br>Cyclophosphamide                              | M/s Shilpa Medicare Ltd.    | <p>The firm presented the proposal for manufacture and marketing of Cyclophosphamide capsules 25 mg and 50mg along with data for the BA/BE</p>   |

| S.No. | File Name & Drug Name, Strength                                  | Firm Name               | Recommendations   |
|-------|--|-------------------------|---|
|       | capsules 25 mg and 50mg  |                         | <p>waiver based on BSC-1 classification and justification for BE waiver .</p> <p>After detailed deliberation, the committee recommended for the approval of grant of permission to manufacture and market Cyclophosphamide capsules 25 mg and 50mg.</p>   |
| 4.    | SND/IMP/22/000086<br><br>Trametanib Tablets<br>0.5 mg and 2.0 mg | M/s Novartis Healthcare | <p>The firm presented their proposal for import and marketing of Trametanib Tablets 0.5 mg and 2.0 mg for additional indication as “Trametinib is indicated, in combination with Dabrafenib, for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options” alongwith their justification, rationale for proposed indication, global approval status and outcome of some Clinical trial data before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of import and marketing of Trametanib Tablets 0.5 mg and 2.0 mg for proposed additional indication as mentioned above.</p> |
| 5.    | SND/IMP/22/000087<br><br>Dabrafenib Capsules<br>50mg & 75 mg     | M/s Novartis Healthcare | <p>The firm presented their proposal for import and marketing of Debrafenib Capsules 50mg &amp; 75mg for additional indication as “Dabrafenib is indicated, in combination with trametinib, for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options” alongwith their justification, rationale for proposed indication, global approval status and outcome of some clinical trial data before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of import and marketing of Debrafenib Capsules 50mg &amp; 75mg for proposed additional indication as mentioned above.</p>   |

| S.No.               | File Name & Drug Name, Strength   | Firm Name                 | Recommendations   |
|---------------------|---|---------------------------|---|
| <b>GCT Division</b> |   |                           |   |
| 6.                  | CT/131/22 Online Submission (34570)<br><br>PF-06741086                      | M/s. Pfizer               | The firm presented Phase III clinical trial protocol No B7841008, dated 29 March 2020 before the committee.<br><br>After detailed deliberation, the committee recommended the grant of permission to conduct the trial with condition to include Pediatric Hematologists as PI or CO-PI in the study. |
| 7.                  | CT/81/22 Online Submission (33473)<br><br>Lorlatinib                        | M/s. Pfizer               | In light of earlier SEC recommendation held on its meeting dated 19.10.2022, the firm presented Phase IV clinical trial protocol No B7461027, dated 22 Jul 2020.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial.                          |
| 8.                  | CT/48/19 Online Submission (20158)<br><br>HD204 to Avastin®                 | M/s. IQVIA                | The firm presented amended clinical trial protocol version-5, dated 04 Jul 2022 before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the study as per amended protocol.   |
| 9.                  | CT/21/20 Online Submission (22014)<br><br>PTG-300                           | M/s. JSS Medical Research | The firm presented their proposal for protocol amendment 9 dated 09 August 2022 before the committee.<br><br>After detailed deliberation, the committee recommended for approval of proposed protocol amendment.  |
| 10.                 | CT/126/22 Online Submission (34327)<br><br>HBI-8000 Combined With Nivolumab | M/s. Novotech             | The firm presented Phase III clinical trial protocol before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial.  |