Recommendations of the SEC (Oncology & Hematology) made in its 127th meeting held on 23.06.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2022/31422 Brentuximab Vedotin	M/s. Takeda Pharmaceuticals Pvt. Ltd.	The firm presented the proposal to conduct Phase IV study before the committee. After detailed deliberation, the committee suggested to increase the number of subjects to not less than 100 and also increase the number of sites accordingly. They should also include Repeat PFT & 2DEcho after completion of 2 Cycles & at the end of treatment. Accordingly, the firm should submit revised protocol for further consideration.
2.	BIO/CT04/FF/2022/31156 Luspatercept	M/s. BMS	The firm presented the proposal to conduct Phase IV study before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study subject to the condition that the number of subjects should be not less than 60. Accordingly, the firm should submit revised protocol to CDSCO for further consideration.
3.	BIO/CT04/FF/2022/31240 Denosumab 120 mg/0.7ml	M/s. Intas	The firm presented the proposal to conduct Phase IV study before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study with the condition that the number of subjects should be not less than 230. Accordingly the firm should submit revised protocol to CDSCO for further consideration.
4.	4-56/MSD/PAC-R-Pemobrolizumab/2020-BD Pembrolizumab Injection 100 mg/4ml (25mg/ml in a single	M/s. MSD Pharmaceuticals Pvt. Ltd.	In light of SEC dated 17.06.2019, firm presented justification with respect to revised package insert. After detailed deliberation, the committee recommended that, firm should include AEs (Haemolytic Anemia and Pure Red

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	vial)		Cell Aplasia) in line with EU SmPC. Accordingly, firm should submit revised package insert to CDSCO for further consideration.
5.	4-40/Astrazeneca/PAC-R Duravalumab Duravalumab	M/s. AstraZeneca Pharma India Limited	The firm didn't turn up for the presentation.
6.	BIO/CT04/FF/2022/30049 Pertuzumab	M/s. Intas	The firm presented the proposal to conduct Phase III study before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial .
7.	4-394/Roche/16-BD (Pt-1) Atezolizumab	M/s. Roche	In light of earlier SEC recommendation dated 11.05.2022 the firm presented the additional data for continuation of indication of metastatic triple negative breast cancer. After detailed deliberation the committee recommended for approval of the said indication inline with EMA approval namely *"Tecentriq in combination with nab-paclitaxel is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have PD-L1 expression ≥ 1% and who have not received prior chemotherapy for metastatic disease"*.
GCT Division			
8.	CT/54/20 Online submission (12774) Trastuzumab Deruxtecan (T-DXd)	M/s. AstraZeneca	The applicant has presented protocol amendment version 3.0 dated 23/07/2021. After detailed deliberation, the committee opined that the firm should present proper justification/rationale vis a vis patient safety for amendment in the protocol for further review by the committee.
9.	CT/99/20 Online submission (15699) Trastuzumab Deruxtecan (T-DXd)	M/s. AstraZeneca	The applicant has presented protocol amendment version 3.0 dated 23/11/2021. After detailed deliberation, the committee opined that the firm should present proper justification/rationale vis a vis patient

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			safety for amendment in the protocol for further review by the committee.