Recommendations of the SEC (Oncology & Haematology) made in its 131st meeting held on 18.08.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/21/000092 Venclexta 10/50/100mg tablets	M/s. Allergan	The proposal was deferred for next meeting.
SND Division			
2.	SND/IMP/22/000046 Abemaciclib Tablets 50/100/150/200 mg	M/s. Eli Lilly	The proposal was deferred for next meeting.
GCT Division			
3.	CT/38/17 Online Submission (17001) PEGylated Factor VIII (BAX 855)	M/s. Baxalta Bioscience	The firm presented the proposed protocol no. 261203, amendment version 08 dated 21-Jun-2021 before the committee. After detailed deliberation, the committee recommended for the proposed protocol amendment with condition that the ISTH guidelines should be followed for the number of bleeding episode for the target joint.
4.	CT/172/21 Online Submission (18529) Elranatamab	M/s. Pfizer	The firm presented the proposed protocol no. C1071007, amendment 1 dated 04-May-2022 before the committee. After detailed deliberation, the committee recommended for the approval of the proposed protocol amendment with condition that the study Investigator's clinical discretion should be on priority for prescribing any concomitant medication (like for COVID-19) to the trial patients as per the protocol.
5.	CT/117/21 Online submission (18497) Datopotamab Deruxtecan (Dato-DXd)	M/s. AstraZeneca	The firm presented the proposed protocol amendment vide TROPION Breast-01 study no. D9268C00001, version 3.0 dated 19-Apr-2022 before the committee. After detailed deliberation, the committee recommended for the conduct of study as per protocol amendment with condition that the firm should provide post trial access of the investigational drug (Dato-DXd) to the trial patients as per Rule 27 of New Drug and Clinical Trials Rules, 2019.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
6.	CT/46/22 Online Submission (31998) Datopotamab Deruxtecan (Dato-DXd)	M/s. AstraZeneca	The firm presented the proposed study protocol no. D926PC00001, version-2.0 (Amendment 1), Dated 13-Jan-2022 (with protocol addendum IND-1, version 1.0 dated 09-Mar-2022) before the committee. After detailed deliberation, the committee recommended for the conduct of the study as per the protocol.
7.	CT/07/21 Online Submission (18947) AZD9833	M/s. AstraZeneca	The firm presented the proposed protocol amendment vide SERENA-4 study no. D8532C00001, amendment-3 (version 4.0) dated 26-Apr-2022 before the committee. After detailed deliberation, the committee recommended for the proposed protocol amendment.
8.	CT/29/22 Online Submission (19279) Durvalumab	M/s. AstraZeneca	In light of earlier SEC recommendation dated 26-May-2022 and CT NOC dated 14-Jun-2022 for protocol no. D910SC00001, version 2.0 dated 16-Nov-2021 (KUNLUN), the firm presented justification before the committee for waiver of condition no. (ii). After detailed deliberation, the committee opined that this is India specific condition so the committee reiterated the earliest decision and did not agree for the waiver of the condition no. (ii).
Biological Division			
9.	4-25/Roche/PAC-R-Atezolizumab/2022-BD Atezolizumab Injection 1200mg/20ml and 840mg/14ml Vials	M/s. Roche Products India Pvt. Ltd.	The proposal was deferred for next meeting.
10.	BIO/CT21/BO/2022/30917 Rituximab	M/s. Zydus LifeSciences Pvt. Ltd	The proposal was deferred for next meeting.