Recommendations of the SEC (Oncology &Haematology) made in its 116th meeting held on 06.01.2022 at CDSCO HQ, New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Introductory Remarks			
New Drug Division			
1.	ND/IMP/21/000093 Ixazomib capsules 2.3mg, 3mg & 4mg	M/s. Baxalta Bioscience India Pvt. Ltd.	The firm didn't turn up for presentation.
2.	ND/IMP/21/000095 Brigatinib 30/90/180 mg	M/s. Baxalta Bioscience India Pvt. Ltd.	The firm didn't turn up for presentation.
SND Division			
3.	SND/IMP/20/000072 Osimertinib Tablets 40 mg and 80 mg	M/s. AstraZeneca	The firm presented proposal for updation of package insert for Osimertinib tablets 40 mg and 80 mg. After detailed deliberation, the committee recommended for approval of the proposed changes in the package insert.
GCT Division			
4.	CT/10/18 Online Submission (11200) Atezolizumab	M/s. Roche	The firm didn't turn up for presentation.
5.	CT/07/21Online Submission (11968) AZD9833	M/s. AstraZeneca	The firm presented Protocol Amendment 2.0 dated 16 March 2021. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial with the amended protocol.
6.	CT/76/21 Online Submission (25705) Savolitinib Plus Durvalumab Versus Sunitinib&Durvalumab	M/s. Labcorp	The firm didn't turn up for presentation.
7.	CT/104/21 Online Submission (27482) LY348-4356	M/s. Eli Lilly	The firm presented Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
8.	CT/60/19 Online Submission (13157) Concizumab	M/s. Novo-Nordisk	The firm presented the proposal to increase the number of subjects from 12 to 18 from India only under the EXPLORER 8 study protocol no. NN7415-4307, Version 5.0dt 25MAR2021. After detailed deliberation, the committee noted that the firm has already enrolled 17 subjects from India and the recruitment to the trial closed. The firm now proposed for the retrospective approval of the increase in number of subjects from India. In view of the enrollment being competitive and 17 subjects have already been enrolled in the study from India, the committee recommended for retrospective approval of additional 05 subjects from India (i.e. from 12 to 17).
9.	CT/16/20 Online Submission (13170) Azacitidine (MBG453)	M/s. Novartis	The firm presented the proposed protocol amendment version 2.0 dated 14JUL2021 under the Phase III protocol no. CMBG453B12301 before the committee. After detailed deliberation, the committee recommended for approval of the proposed amendment with conditions that the exclusion criteria no#9 (protocol section 5.2) will not be amended because the study enrollment already completed on 15DEC2021.
10.	CT/143/21 Online Submission (28819) Hydrogen peroxide	M/s. IQVIA	The firm presented Phase II clinical trial protocol before the committee. After detailed deliberation, the committee opined that the proposal may be deliberated in presence of MD-Radio-Therapy (RT) or Radiation Oncology Expert.
11.	CT/147/21 Online Submission (28905) Capmatinib	M/s. Novartis	The firm presented the proposed Phase III GEOMETRY-E study protocol no. CINC280L112301 before the committee. After detailed deliberation, the committee recommended for grant

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			of permission to conduct the proposed study.
12.	CT/86/20 Online Submission (12408) Durvalumab	M/s.AstraZeneca	The firm didn't turn up for presentation.