Recommendations of the SEC (Oncology & Haematology) made in its 117th meeting held on 27.01.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/21/000323 Tranexamic Acid Spray 10% w/v	M/s. Shilpa Medicare	In light of earlier recommendation of the committee dated 09.12.2021 & 10.12.2021, the firm presented their proposal with modified Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial study as presented.
Biological Division			
2.	4-394/Roche/16-BD (Pt-I) Atezolizumab	M/s. Roche Products (India) Pvt.Ltd	The firm presented the proposal informing the committee regarding the voluntary withdrawal of metastatic urothelial carcinoma indication for Atezolizumab injection in USA. The committee noted that the accelerated approval in USA was accorded to the firm based on results of Phase II (IMvigor 210). However, the indication has been voluntarily withdrawn in-consultation with US FDA since the confirmatory clinical trial (Phase III study – IMvigor211) did not meet the primary endpoint. The committee noted that the indication of metastatic urothelial carcinoma is still continued in other countries. After detailed deliberation, the committee opined that the results of trials may be deliberated in presence of urologist and uro-surgeon for taking decision in the matter.
3.	4-394/Roche/16-BD(Pt-I) Atezolizumab	M/s. Roche Products (India) Pvt.Ltd	The firm presented the proposal informing the committee regarding the voluntary withdrawal of metastatic triple negative breast cancer (mTNBC) indication for Atezolizumab injection in USA. The committee noted that the accelerated approval in USA was accorded to the firm based on results of IMpassion130.

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			However, the indication has been voluntarily withdrawn in-consultation with US FDA since the confirmatory clinical trial (Phase III study – Impassion 131) did not meet the primary endpoint. After detailed deliberation, the committee opined that the results of trials may be deliberated in presence of onco-surgeon for taking decision in the matter.
4.	4-30/Roche/PAC-R-Atezilizumab/19-BD(Pt-II) Atezolizumab	M/s. Roche Products (India) Pvt.Ltd	The firm didn't turn up for presentation.
5.	4-350/BMS/160BD (Part-I) Nivolumab	M/s. Bristol Myers Squibb	The firm didn't turn up for presentation.
6.	BIO/CT/21/000010 Recombinant Human Albumin	M/s. Shilpa Biologicals Private Limited	The firm presented the amendments in the already approved Phase I clinical trial. After detailed deliberation, the committee recommended for grant of approval to conduct the study as per proposed amendments subject to the condition that the principal investigator should be MBBS, MD and the trial should also include a co-investigator who should be a clinical pharmacologist. Accordingly, the firm should submit revised protocol to CDSCO for further consideration.
GCT Division			
7.	CT/76/21 Online Submission (25705) dated 07/07/2021 Savolitinib Plus Durvalumab Versus Sunitinib & Durvalumab	M/s. Labcorp	The firm presented the proposed Phase III SAMETA study protocol no.: D5086C00001; Version: 1.0, Dated 26-FEB-2021 and Addendum IND-1, Version: 1.0 dated 18-OCT-2021 before the committee. After detailed deliberation, the committee opined that the firm should submit the Phase II study data with the IP for consideration by the committee.
8.	CT/136/21 Online Submission (28557) dated 15/10/2021 Belantamab	M/s. GSK	The firm presented the proposed Phase II DREAMM-14 study protocol no.: 209628; Version: 1.0; Date: 06-JAN-2022 before the committee.

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	mafoclotin		After detailed deliberation, the committee opined that the firm should submit the following: 1. Justification for dose modification criteria as per protocol, 2. Justification for randomization of subjects in the proposed open label study to avoid study centre-bias as the applicant has proposed 15 subjects from 13 sites in the country. The committee also opined that the proposal will be further re-deliberated in presence of ophthalmology expert.
9.	CT/143/21 Online Submission (28819) dated 08/11/21 Hydrogen peroxide	M/s. IQVIA	In light of earlier SEC recommendation dated 06-Jan-2022, the firm presented their justification before the committee in presence of expert Radiotherapist. After detailed deliberation, the committee recommended for grant of permission to conduct the study as presented.
10.	CT/150/21 Online Submission (29056) dated 16/11/21 Elranatamab (PF-06863135)	M/s. Pfizer	The proposal was deferred for the next SEC meeting.