Recommendations of the SEC (Oncology & Haematology) made in its 124th meeting held on 11.05.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/22/000015 Selpercatinib 40 MG & 80 mg Capsules	M/s. Eli Lilly Kinsale	The firm presented their proposal for import and marketing of the drug Selpercatinib 40 mg and 80 mg capsules along with justification for clinical trial waiver before the committee. The committee noted that the drug is already approved in US, EU, Canada, Japan, United Kingdom etc., and the drug is indicated for a disease which is serious and life threatening disease and there is an unmet medical need in the country. After detailed deliberation, the committee recommended for grant of permission to import and marketing of Selpercatinib 40 mg and 80 mg capsules subject to the following conditions: 1. The firm should increase number of Indian subjects in ongoing global clinical trial in the country. 2. The firm should conduct Phase IV clinical trial in the country for which the protocol should be submitted to CDSCO within two months of approval of the drug for further review by the committee.
2.	ND/CT/000090 Darulotamide Tablet 300 MG	M/s Bayer Pharmaceuticals Pvt. Ltd.	The firm didn't turn up for presentation.
Biological Division			
3.	4-394/Roche/16-BD (Pt-I) Atezolizumab	M/s. Roche	In light of earlier SEC recommendation dated 24.02.2022, the firm presented the proposal for continuation of two indications namely 1. Metastatic triple negative breast cancer which is voluntarily withdrawn in US in consultation with USFDA. 2. Change in indication of locally advanced or metastatic Urothelial Carcinoma in line with USFDA approval. After detailed deliberation, the committee recommended that there may be no objection for change in indication of locally advanced or metastatic Urothelial Carcinoma indication wording in line

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			with USFDA approval. For the indication of metastatic triple negative breast cancer, the committee recommended that the firm should submit the following: 1. Documentary evidence for submission of data of Phase III study IMpassion131 already reported to regulatory authorities such as EU, UK, Japan, and Switzerland. 2. Efficacy results with current status of the Phase III study IMpassion130, Indian patients subsets along with real world data.
4.	BIO/CT/20/000058 (Pt-I) Nivolumab and Ipilimumab	M/s. BMS	The firm presented the proposal for amendment in Phase IV protocol. After detailed deliberation, the committee recommended for grant of protocol amendment version 01 with the condition that the firm should submit the details of inflammatory markers to CDSCO along with rationale for inclusion in the protocol.
SND Division			
5.	SND/MA/22/000128 Capecitabine Dispersible tablets 150mg, 500mg & 1000mg	M/s Shilpa Medicare Limited	The firm presented their proposal for manufacturing and marketing of Capecitabine Dispersible tablets 150mg, 500mg & 1000mg along with the BE study report before the committee for approval. After detailed deliberation, the committee recommended for grant of permission for the manufacturing and marketing of Capecitabine Dispersible tablets 150mg, 500mg & 1000mg for the following indications: • For the treatment of patients with metastatic colorectal cancer. • For the treatment of metastatic breast cancer after failure of Paclitaxel and Anthracycline containing chemotherapy regimen.
GCT Division			
6.	CT/23/22 Online Submission (30859) Durvalumab+	M/s. AstraZeneca	The firm presented the proposed Phase III clinical trial protocol no- D910VC00001, version: 1.0 dated 05Nov2021 (EMERALD-3) before the committee.

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	Tremelimumab + Lenvatinib		After detailed deliberation, the committee recommended for grant of permission to conduct the proposed trial. Considering the high prevalence of the disease in the country, the committee suggested to increase the number of subjects to 34, from proposed 24 subjects in India.
7.	CT/75/17 Online Submission (15998) Durvalumab, Tremelimumab, Sorafenib	M/s. AstraZeneca	The firm presented the proposed amendment in the HIMALAYA trial protocol no. D419CC00002, amendment version 7.0 dated 22-Sep-2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.