Recommendations of the SEC (Oncology & Haematology) made in its 120th meeting held on 09.03.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/22/000004 Entrectinib capsules 100mg and 200mg	M/s. Roche products(I)	The firm didn't turn up for presentation.
2.	ND/MA/22/000033 Idelalisib 150mg & 100mg Tablets	M/s. Natco Pharma Limited	The firm presented their proposal for manufacture and marketing of the drug with local clinical trial waiver and result of BE study before the committee. The committee noted that the drug is already approved in countries like US, EU, Canada and also the drug is an orphan drug & indicated for 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 manufacture and market the drug for the proposed indication subject to condition that the firm should conduct a Phase IV clinical trial for which protocol should be submitted within 3 months of approval of the drug for review by the committee. The drug should be sold by retail under the prescription of the Oncologist only.
FDC Division			
3.	FDC/MA/22/000054 Resveratrol 5.6mg+Copper (as copper glycinate) 0.56mcg capsules	M/s. Inventia Healthcare Ltd.	The firm presented their proposal before the committee to conduct Phase III CT studies and BE study waiver. After detailed deliberation, the committee recommended that the firm should initially submit and present the detailed animal toxicity data indicating the MTD as well as the equivalent human dose with justification. The firm should also submit justification for BE study waiver. Based on this, the committee can further consider the requirement of conducting Phase II and Phase III trial.

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GCT Division			
4.	CT/76/21 Savolitinib Plus Durvalumab Versus Sunitinib & Durvalumab	M/s. Labcorp	In light of earlier SEC recommendation dated 27-JAN-2022, the firm presented the Phase III-SAMETA study vide protocol no. D5086C00001 version 1.0 dated 26-FEB-2021 and addendum IND-1, version: 1.0 dated 18-OCT-2021 before the committee. **Assessment of risk versus benefit**: Overall the benefit/risk assessment supports the further investigation of Savolitinib plus Durvalumab versus Sunitinib in participants with MET-driven, unresectable and locally advanced or metastatic PRCC. **Innovations Vs existing therapeutic option:** The SAMETA study is designed to evaluate the efficacy and safety of the Savolitinib plus Durvalumab combination compared with Sunitinib in first-line participants with unresectable and locally advanced or metastatic PRCC that is MET driven without co-occurring FH mutations. The study will also investigate the contribution of Durvalumab to the Savolitinib plus Durvalumab combination. **Unmet Need**: Available antitumor therapies have all been approved for the broader condition, RCC, with limited efficacy data obtained in PRCC. Effective therapies for PRCC represent an unmet medical need. After detailed deliberation, the committee recommended for grant of permission to conduct the study.
5.	CT/136/21 Belantamab Mafodotin	M/s. GSK	In light of the earlier SEC recommendations dated 27-JAN-2022 and 24-FEB-2022, the firm presented the Phase IIa (DREAMM 14) study protocol no. 209628, version-01 dated 21-JAN-2022 before the committee in presence of Ophthalmology expert. After detailed deliberation, the committee recommended for grant of permission to conduct the study with the following conditions: 1) The study sites must have

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			Ophthalmologist as Co-Investigator or Sub-Investigator. 2) In case of an adverse event, the study participant(s) should be followed up to full length or till resolution of AE by the study Ophthalmologist.
6.	CT/84/19 Goserelin 3.6 mg Injection	M/s. Lambda Therapeutic	The firm presented their proposal for amendment for protocol 1046-18 version 3.0 dated 25-Oct-2021. After detailed deliberation, the committee recommended approval for the proposed protocol amendment.
7.	CT/162/21 Palbociclib	M/s. Pfizer	The firm presented their proposal for Phase I/II CT before the committee. **Assessment of risk vs. benefit to the patients:** the safety profile of the study drugs from preclinical toxicology, including repeat dose toxicity study justify the conduct of the trial. **Innovation vis-à-vis existing therapeutic option:** the purpose of the study is to evaluate Palbociclib (ibrance®) in combination with Irinotecan and Iemozolomide and/or in combination with Topotecan and cyclophosphamide in pediatric patients with recurrent or refractory solid tumors **Unmet medical need in the country:** the test drug may potentially provide benifit in pediatric patients with recurrent or refractory solid tumors. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II clinical trial only.
8.	CT/21/22 TK-90	M/s. SIRO	The firm presented their proposal for Phase IIa before the committee. **Assessment of risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity study and Phase I &II clinical study data justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic option:** The purpose of the study is to establish pilot efficacy compared to TK 90 placebo for TK-90 as

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			an anti-mucositis agent when administered weekly for 7 consecutive weeks by IV infusion to patients with non metastatic SCCHN who are scheduled to receive radiation for their disease. **Unmet Medical need in the country:** The test drug may potentially provide treatment in patients with non-metastatic SCCHN. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that the firm should include response assessment of IMP as a secondary end point in non-operative patients who will receive definitive radiation therapy.
BA/BE Division			
9.	12-09/2022/BA-BE/Misc-03/DC Paclitaxel Protein-Bound Particles for Injectable Suspension (albumin-bound) 100 mg/vial	M/s. Cipla Limited, Mumbai-400013	The firm presented amended study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the amended protocol.