Recommendations of the SEC (Oncology & Haematology) made in its 121st meeting held on 24.03.2022 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 (India) Pvt. Ltd	The firm presented their proposal for import and marketing of the drug Entrectinib capsules 100mg and 200mg along with local clinical trial waiver before the committee. The committee noted that the drug is already approved in US, EU, Japan and also the drug is an orphan drug indicated for serious and life threatening diseases and there is an unmet medical need in the country. Also the firm has submitted two protocols (Protocol No M041552 & Protocol No BO42777) for permission to conduct two global clinical trials, of which the firm has already received permission for (Protocol No M041552) on 14.3.2022. After detailed deliberation, the committee recommended for grant of permission to import and market Entrectinib capsules 100mg and 200mg subject to condition that the firm should conduct Phase IV clinical trial in the country in 50 patients for which the protocol should be submitted to CDSCO within two months of approval of the drug for review by the committee.
Biological Division			
2.	04-29/Pfizer /PAC-R-Nonacogalfa/2020-BD (Pt-1) Nonacog Alfa (Recombinant Coagulation Factor IX)	M/s. Pfizer Products India Pvt. Ltd	The firm presented their proposal for revision in the Package insert w.r.t. posology of drug before the committee. After detailed deliberation, the committee recommended for approval of the changes proposed in the posology. The firm should submit a fresh application for revision in the already approved indication in-line with US FDA.
GCT Division			
3.	CT/22/22 Online Submission (30824) TK-90	M/s. Siro Clinpharm	The firm presented their Phase IIa clinical trial proposal before the committee. **Assessment of risk versus benefit to the**

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			patients-The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic option:-** To evaluate pilot efficacy of an IV infusion of TK-90 compared to an infusion of TK-90 placebo as a mucositis preventive agent in patients with colorectal cancer receiving 5-FU/LV treatment for their disease. **Unmet medical need in the country-** The test drug is used for colorectal cancer receiving 5-FU/LV treatment for their disease. The committee also opined that the combination of 5FU and LV is very infrequently used in clinical practices. After detailed deliberation, the committee recommended for grant of permission to conduct the study as presented by the firm.
4.	CT/164/21 Online Submission (29467) Zanidatamab (ZW25)Tislelizumab (BGB-A317)	M/s. PPD	The firm presented their clinical trial data in light of the earlier SEC recommendation dated on 09.02.2022, for conducting Phase II/III clinical trial in targeted population. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial.