Recommendations of the SEC (Oncology & Haematology) made in its 122nd meeting held on 12.04.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT/20/000058 Romiplostim injection 250mcg/vial	M/s. Enzene Biosciences Ltd.	The firm presented the proposal for conduct of Phase IV clinical study in compliance with the condition of marketing authorization. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the protocol presented.
2.	BIO/CT/20/000058 (Pt-I) Nivolumab and Ipilimumab	M/s. BMS	The firm didn't turn up for the presentation.
3.	BIO/CT/20/000088 Recombinant human serum albumin 20%	M/s. Lazuline Biotech Private limited	The firm presented the proposal to conduct Phase I clinical study along with the animal toxicity and head to head characterization data. The committee noted that the drug is not yet approved anywhere and therefore the Phase I study design should generate safety and tolerability data at various dose levels before carrying out Pk/Pd study as per NDCT Rules, 2019. Further, the principal investigator should have experience in conducting Phase I studies and should be MD Pharmacology/clinical Pharmacologist. Further, the study site should be suitably equipped to carry out Phase I study. After detailed deliberation, the committee recommended that the firm should submit revised study protocol incorporating the above suggestions for further consideration.
SND Division			
4.	SND/IMP/22/000007 Olaparib film-coated tablets 100 mg and 150 mg	M/s. AstraZeneca Pharma Limited	The firm presented their proposal for import and marketing of Olaparib film-coated tablets 100mg & 150mg (Additional Indication) for monotherapy for the adjuvant treatment of adult patients with BRCA-mutated HER2-negative high risk early breast cancer who have previously been treated with neo adjuvant or adjuvant chemotherapy.

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			After detailed deliberation, the committee opined that the firm should submit CSR of the ongoing Phase IV clinical trial in already approved indication (vide permission no. IMP-ND-189/2018 dated 13.08.2018) for taking further action in the matter.
GCT Division			
5.	CT/88/18 Online Submission (15491) Durvalumab+Bevacizumab	M/s. AstraZeneca	The firm presented protocol number D933GC00001 amendment version 4.0 dated 16-Nov-2021 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment.
6.	CT/10/18 Online Submission (11200) Atezolizumab	M/s. Roche	In light of earlier SEC recommendation dated 07/10/21 & 08/10/21, the firm presented protocol number WO40242 amendment version 9.0 dated 07-Jan-2021 before the committee. The applicant informed the committee that the treatment period is over and only follow up period is going on. After detailed deliberation, the committee did not recommend for approval of the said protocol amendment as at this stage there is no need for proposed changes in protocol i.e. permission for use of immunosuppressive medication since treatment period was over.
7.	CT/95/19 Online Submission (14753) Selpercatinib	M/s. Eli Lilly	The firm did not turn up for presentation.
8.	CT/55/21 Online Submission (13862) TAR-200	M/s. PRA	The firm presented the protocol amendment version 2.0 dated 02/08/2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
9.	CT/151/21 Online Submission (28818) PF-114	M/s. Edenwell Therapeutics	The firm presented their proposal for Phase III clinical trial 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 , Phase I clinical study justify the conduct of the

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			trial. **Innovation vis-à-vis Existing Therapeutic option:** The purpose of the study is to evaluate efficacy and safety of PF-114 versus Imatinib at 600 mg and 800 mg daily in adult patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in the chronic phase (CP) resistant to Imatinib at daily dose of 400 mg or 600 mg. **Unmet Medical need in the country:** The test drug is useful in adult patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in the chronic phase (CP) resistant to Imatinib at daily dose of 400 mg or 600 mg. After detailed deliberation, the committee recommended for grant of permission for conduct of the proposed clinical trial with condition that "the firm should enroll initial 50 subjects from India and submit their safety data along with DSMB report for further review by the committee for further continuation of the trial".
10.	CT/160/21 Online Submission (29361) SCO-120	M/s. Sun Pharma	In light of earlier SEC recommendation dated 09.02.2022, the firm presented their justification before the committee. The committee noted that the IP- SC0-120 was developed indigenously in the country and the applicant has filed IND application to USFDA. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed clinical trial.
11.	CT/16/22 Online Submission (30457) Concizumab	M/s. Novo-Nordisk	The firm presented their proposal for Phase IIIa clinical trial 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 & Phase 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 superiority of

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			Concizumab prophylaxis in Concizumab-naïve children <12 years with haemophilia A or B with inhibitors compared to their previous on demand treatment on the number of treated spontaneous and traumatic bleeding episodes. **Unmet medical need in the country:** The test drug may potentially provide treatment in children <12 years with haemophilia A or B with inhibitors. After detailed deliberation, the committee recommended for grant of permission to conduct the study.
12.	CT/26/22 Online Submission (30811) Itolizumab (EG001)	M/s. Bioinnovat	The firm presented their proposal for Phase III clinical trial before the committee. After detailed deliberation, the committee opined that the proposal should be re-deliberated in presence of clinical hematologist/Immunohematologist in upcoming SEC meeting.