Recommendations of the SEC (Oncology & Haematology) made in its 118th meeting held on 09.02.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/21/000093 Ixazomib capsule 2.3mg, 3mg, & 4mg	M/s. Baxalta Bioscience India Pvt. Ltd	The firm presented their proposal for import and marketing of the drug Ixazomib 2.3mg, 3mg, & 4mg 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 and the drug is indicated for a disease which is serious and life threatening 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 Ixazomib 2.3mg, 3mg, & 4mg capsules subject to condition that 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 review by the committee.
2.	ND/IMP/21/000095 Brigatinib 30/90/180 mg	M/s. Baxalta Bioscience India Pvt. Ltd.	The firm presented their proposal for import and marketing of the drug Brigatinib 30/90/180 mg Tablet along with justification for clinical trial waiver before the committee. The committee noted that the drug is already approved in US, EU, Canada, Japan and the drug is indicated for a disease which is serious and life threatening 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 Brigatinib 30/90/180 mg Tablet subject to condition that 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 review by the committee.

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3.	ND/IMP/21/000092 Venetoclax Film coated tablet 10/50/100 mg	M/s Allergan healthcare India Pvt Ltd.	The firm presented their proposal for import and marketing of the drug Venetoclax 10/50/100 mg film coated tablets along with justification for clinical trial waiver before the committee. The committee noted that the drug was approved and designated as Orphan Drug for treatment of AML in US, Japan and Australia & for CLL in US , Russia, South Korea, Mexico, Switzerland and the drug is indicated for a disease which is serious and life threatening and there is an unmet medical need in the country. After detailed deliberation, the committee recommended for the grant of permission to import and market the drug with local clinical trial waiver subject to the condition that the firm should conduct a Phase IV clinical trial for which protocol should be submitted within two months of approval of the drug for review by the committee.
4.	12-01/19-DC(Pt-208) Thalidomide	PGIMS, New Delhi	The applicant presented their proposal before the committee. During presentation, the applicant stated that the approval from site Ethics Committee will be obtained. After detailed deliberation, the committee opined that there should be no objection for the conduct of academic clinical trial subject to the following conditions: 1. The applicant should include blood transfusion specialist in each site. 2. The applicant should submit approval from site Ethics committee to CDSCO before initiation of the study.
SND Division			
5.	SND/IMP/21/000111 Dabrafenib capsules 50 mg and 75 mg	M/s. Novartis Healthcare	The firm presented their proposal for import and marketing of the drug Dabrafenib capsules 50 mg and 75 mg for

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			an additional indication, along with justification for clinical trial waiver before the committee. The committee noted that the drug is already approved in US, Australia & Singapore etc. for the proposed additional indication. After detailed deliberation, the committee recommended for grant of permission to import and marketing of Dabrafenib capsules 50 mg and 75 mg for the following indication Dabrafenib in combination with trametinib for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory loco regional treatment options.
6.	SND/IMP/21/000110 Dabrafenib capsules 50 mg and 75 mg	M/s. Novartis Healthcare	The firm presented their proposal for import and marketing of the drug Dabrafenib capsules 50 mg and 75 mg for an additional indication, along with justification for clinical trial waiver before the committee. The committee noted that the drug is already approved in US, EU, Japan, Canada etc for the proposed additional indication. After detailed deliberation, the committee recommended for grant of permission to import and marketing of Dabrafenib capsules 50 mg and 75 mg for the following indication Dabrafenib in combination with trametinib for the adjuvant treatment of patients with melanoma with BRAF V600E orV600K mutations, as detected by an appropriate test, and involvement of lymphnode (s), following complete resection.
7.	SND/IMP/21/000109 Trametinib tablets 0.5 mg and 2 mg	M/s. Novartis Healthcare	The firm presented their proposal for import and marketing of the drug Trametinib tablets 0.5 mg and 2 mg for an additional indication, along with justification for clinical trial waiver before the committee.

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			The committee noted that the drug is already approved in US, Australia & Singapore etc for the proposed additional indication. After detailed deliberation, the committee recommended for grant of permission to import and marketing of Trametinib tablets 0.5 mg and 2 mg for the following indication Trametinib in combination with dabrafenib for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.
8.	SND/IMP/21/000108 Trametinib tablets 0.5 mg and 2 mg	M/s. Novartis Healthcare	The firm presented their proposal for import and marketing of the drug Trametinib tablets 0.5 mg and 2 mg for an additional indication, along with justification for clinical trial waiver before the committee. The committee noted that the drug is already approved in US, EU, Japan, Canada etc for the proposed additional indication. After detailed deliberation, the committee recommended for grant of permission to import and marketing of Trametinib tablets 0.5 mg and 2 mg for the following indication Trametinib is indicated, in combination with dabrafenib, for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations as detected by an appropriate test, and involvement of lymph node(s).
GCT Division			
9.	CT/88/19 Online Submission (13463) PF-06741086	M/s. Pfizer	The firm presented their proposal for protocol amendment B7841005, Amendment 6, dated 13-July-2021. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.
10.	CT/150/21 Online Submission (29056) Elranatamab (PF-06863 135)	M/s. Pfizer	The firm presented Phase III clinical trial protocol C1071005 (Final protocol amendment 01 dated 11/10/2021) before the committee.

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			Assessment of risk versus benefit to the patient- The safety profile of trial drug from various pre-clinical toxicity studies and clinical studies, may justify the conduct of the proposed trial. **Innovations Vs existing therapeutic option-** The primary objective of the study is to evaluate the efficacy and safety of Elranatamab (PF-06863135) monotherapy and Elranatamab + Daratumumab versus Daratumumab + Pomalidomide + Dexamethasone in participants with relapsed/refractory multiple myeloma who have received at least 1 prior line of therapy including Lenalidomide and a proteasome inhibitor **Unmet medical need in the country-** There is a need for new, effective, and safe therapies for treatment of relapsed/refractory multiple myeloma. The trial drug may be an alternative treatment option in subject with relapsed/refractory multiple myeloma. The committee noted that Phase I & II clinical trial of test drug are ongoing. After detailed deliberation, the committee recommended for grant of permission to conduct the part 2 of the proposed study as presented by the firm subject to the following conditions: 1. The firm should submit CSR of Phase I and II studies to CDSCO. 2. The firm should submit DMC recommendations to CDSCO as per protocol. 3. Amylase and Lipase testing should be done during screening visit and for exclusion of subjects with bacterial infection i.e. Tuberculosis, QuantiFERON-TB Gold test to be done at screening. 4. All SAEs including death irrespective of its cause should be reported to CDSCO as SAE.
11.	CT/172/21 Online Submission (29624)	M/s. Pfizer	The firm presented their Phase III clinical trial proposal before the committee.

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	Elranatamab		**Assessment of risk versus benefit to the 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-** Elranatamab (PF-06863135) versus lenalidomide in patients with newly diagnosed multiple myeloma who are minimal residual disease-positive after undergoing autologous stem-cell transplantation **Unmet medical need in the country-** The test drug used in patients with newly diagnosed multiple myeloma who are minimal residual disease-positive after undergoing autologous stem-cell transplantation. After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions- 1. Amylase and Lipase testing should be done during screening visit and for exclusion of subject with bacterial infection i.e. Tuberculosis, QuantiFERON-TB Gold test shall done at screening. 2. All SAEs including death irrespective of its cause shall be reported to CDSCO as SAE.
12.	CT/160/21 Online Submission (29361) SCO-120	M/s. Sun Pharma	The firm presented their proposal for Phase I clinical trial before the committee. After detailed deliberation, the committee opined that the firm should submit pre-clinical and clinical Phase I (study no. SCO-120-19-18) data to CDSCO for further review by the committee for consideration of the proposed study.
13.	CT/164/21 Online Submission (29467) Zanidatamab (ZW25), Tislelizumab (BGB-	M/s. PPD	The firm presented their clinical trial Phase III protocol before the committee. The committee noted that the test drugs-

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	A317)		Zanidatamab and Tislelizumab are not approved in India and the firm has proposed directly Phase III clinical trial. After detailed deliberation, the committee recommended that the firm should conduct Phase II/III clinical trial in targeted population and accordingly, submit protocol to CDSCO for further review by the committee.