Recommendations of the SEC (Oncology & Haematology) made in its 138th meeting held on 09.12.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/21/000040 Pralsetinib Capsules 100mg	M/s. Roche	Firm was granted permission to import and market Pralsetinib Capsules 100mg subject to the condition that 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. However, the firm presented its request for consideration of an alternative approach to Phase IV clinical trial. The committee noted that the firm proposed following alternative approach to Phase IV CT: 1. The participation of Indian centres in 5 Phase III global clinical trials which would include total number of 61 Indian patients. 2. The voluntary conduct of Real World Evidence Basket study for tumor and rare condition (TARC) in 40 patients. After detailed deliberation, the committee reiterated its earlier recommendation. Accordingly, the firm should submit Phase IV clinical trial protocol before the committee.
2.	ND/MA/22/000144 Relugolix Tablets 120mg	M/s. Zydus Lifesciences Ltd.	The firm presented its proposal for manufacture and market of drug Relugolix Tablets 120mg along with bioequivalence study protocol and justification for waiver of Phase III clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct BE study as per the protocol presented subject to the condition that the firm should revise the protocol with respect to inclusion criteria to enroll the subjects with higher age group between the age 35-45 years who have completed the family planning. The results of the BE study should be

			presented before the committee for further consideration.
3.	ND/IMP/21/000009 Darolutamide Tablets 300mg	M/s. Bayers Pharmaceuticals Pvt. Ltd.	The firm presented its proposal for amendment of the warning statement of Darolutamide300mg Tablet. After detailed deliberation, the committee recommended for approval of the proposed changes in warning statement from "To be sold by retailer under prescription of Oncologist only" to "To be sold by retailer under prescription of Oncologist and Urologist only".
4.	ND/IMP/22/000004 Entrectinib 100mg and 200mg capsules	M/s. Roche	Firm was granted permission to import and market Entrectinib capsules 100mg & 200mg subject to condition that the firm should conduct Phase IV clinical trial in the country in 50 patients for which they should submit clinical trial protocol within 2 months of approval of the drug for review by the committee. However, the firm presented its request for consideration of an alternative proposal to Phase IV clinical trial. The committee noted following alternative proposal to Phase IV CT study of the firm; 1. The participation of Indian centres in global clinical trials: 2 Phase III studies would include Indian patients for a total no. of 18 patients. 2. The voluntary conduct of a Pilot Study for tumour agonistic and rare conditions (TARC): a cohort of additional patients would be recruited from a large apex centre which routinely uses NGS screening panel that include the mutations of interest and from HCPs pan-India in a RWE basket study. After detailed deliberation, the committee reiterated its earlier recommendation. Accordingly, the firm should submit Phase IV clinical trial protocol before the committee.
Biological Division			
5.	BIO/CT18/FF/2022/34250	M/s. Johnson and Johnson	The firm presented the proposal to import and marketing of the drug Teclistamab sterile liquid in vials 30mg/vial and

	Teclistamab		90mg/vial indicated for treatment of adult patients with relapsed or refractory multiple myeloma who have received at least three prior therapies including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody with local clinical trial waiver. The firm presented the results of a Phase 1/2, first-in-human, open-label, dose escalation study of teclistamab, a humanized BCMA×CD3 bispecific antibody, in subjects with relapsed or refractory multiple myeloma(MajesTEC-1) conducted in multiple countries including US and EU. The committee noted that the drug is currently approved in EU and US under conditional approval. The committee also noted that two global clinical trials (Study 64007957MMY3005 and 64007957MMY3006) are planned in which India is one of the participating countries. After detailed deliberation, the committee recommended that the firm should submit patients characteristics along with transplant history if any, treatment details and details of approval of the drug in EU and US for further deliberation.
SND Division			
6.	SND/IMP/22/000087 Dabrafenib Capsules 50mg & 75 mg	M/s. Novartis Healthcare	The firm did not turn up for presentation.
7.	SND/IMP/22/000086 Trametanib Tablets 0.5 mg and 2.0 mg	M/s. Novartis Healthcare	The firm did not turn up for presentation.
GCT Division			
8.	CT/39/22 Online Submission (31692) CJDQ443	M/s. Novartis	The applicant presented Phase III clinical trial protocol no CJDQ44B12301, KontRASt-02, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions- 1. The applicant should submit updated safety and efficacy data from ongoing

			Phase Ib/II study before the committee for review. 2. The applicant and investigators should report all death irrespective of its cause i.e. PD as SAE to CDSCO as per NDCTR 2019 during the conduct of the study.
9.	CT/25/16 Online Submission (5331) Abemaciclib	M/s. Eli Lilly	The applicant presented protocol amendment no I3Y-CR-JPBQ (h) dated 22-03-2021 before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.
10.	CT/121/20 Online Submission (20751) NNC0365-3769 (Mim8)	M/s. Novo-Nordisk	The applicant presented protocol amendment version 9.0 dated 26-08-2022 under protocol no NN7769-4514-FRONTIER 2 before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.
11.	CT/103/21 Online Submission (21201) Trastuzumab Deruxtecan	M/s. AstraZeneca	The applicant presented its proposal for waiver of CT NOC condition no1 – i.e the firm needs to increase number of subjects to at least 25 from India before the committee. After detailed deliberation, the committee did not recommend the waiver of the earlier CT NOC condition no. 1.
12.	CT/104/22 Online Submission (33947) NNC0365-3769 (Mim8)	M/s. Novo-Nordisk	The applicant presented Phase IIIa clinical trial no NN7769-4516-FRONTIER 3 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that the applicant should submit interim efficacy and safety data of first part of the study for further review by the committee and once data would be reviewed by the committee, trial might be continued.
13.	CT/76/21 Online Submission (20357) Savolitinib	M/s. Labcorp	The applicant presented protocol amendment version 3.0 dated 14-12-2021 before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.
14.	CT/123/22 Online Submission (34313) Datopotamab	M/s. AstraZeneca	The applicant presented Phase III clinical trial protocol no D926NC), version 1.0 dated 15-07-2022, local clinical trial protocol addendum IND-1, version 1.0 dated 11-08-2022 before the committee.

	Deruxtecan (Dato-DXD)		After detailed deliberation, the committee recommended for grant of permission to conduct the study.
15.	CT/118/20 Online Submission (19919) Darolutamide	M/s. Bayer Pharmaceutical	In light of earlier SEC meeting dated 08-09-2022, the applicant presented justification for increase of global sample size with its chronological orders along with protocol amendment version 2.0 dated 28-June-2022. After detailed deliberation, the committee recommended for approval of proposed protocol amendment subject to condition that there is no change in approved number of subjects from India owing to the proposed protocol amendment.
16.	CT/81/21 Online submission (20888) Galinpepimut-S (GPS)	M/s. PPD	The applicant presented protocol amendment 3.0 dated 24-08-2022 under the study protocol no. SLSG18-301 before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment. Dr. C.K. Bose did not participate in the deliberation.