Recommendations of the SEC (Oncology & Haematology) made in its 132nd meeting held on 08.09.2022 & 13.09.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/19/000020 Lorlatinib Tablets 25mg and 100mg	M/s. Pfizer Product Pvt. Ltd.	The firm presented their proposal for amendment of warning condition before the committee. After detailed deliberation, the committee reiterated the earlier SEC recommendation with same warning condition "to be sold by retail on the prescription of Oncologist only".
2.	12-171/2011-DC Crizotinib Capsules 200mg and 250mg	M/s. Pfizer Product Pvt. Ltd.	The firm presented their proposal for amendment of warning condition before the committee. After detailed deliberation, the committee reiterated the earlier SEC recommendation with same warning condition "to be sold by retail on the prescription of Oncologist only".
3.	12-37/2012-DC Axitinib Tablets 1mg and 5mg	M/s. Pfizer Product Pvt. Ltd.	The firm presented their proposal for amendment of warning condition before the committee. After detailed deliberation, the committee reiterated the earlier SEC recommendation with same warning condition "to be sold by retail on the prescription of Oncologist only".
4.	ND/IMP/19/000039 Dacomitinib 15 mg & 30 mg Tablets	M/s. Pfizer Product Pvt. Ltd.	The firm presented their proposal for amendment of warning condition before the committee. After detailed deliberation, the committee reiterated the earlier SEC recommendation with same warning condition "to be sold by retail on the prescription of Oncologist only".
5.	ND/IMP/21/000092 Venetoclax Tablets 10, 50 & 100mg	M/s. Allergan	The firm was granted permission on 01.07.2022 for import of drug for sale and distribution in the country with condition that the firm should conduct Phase IV clinical trials. The firm presented their proposal for waiver of Phase IV CT of Venetoclax Tablets 10 mg, 50mg, and 100 mg.

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			After detailed deliberation, the committee opined that the firm has no safety data on Indian population and hence recommended that the request of the firm for Phase IV CT waiver could not be considered.
6.	ND/IMP/21/000077 Fosnetupitant and Palonosetron 235mg/0.25 mg concentrate for solution for infusion	M/s. Glenmark Pharmaceutical Ltd.	The firm presented their proposal for waiver of Phase IV clinical trial before the committee. After detailed deliberation, the committee opined that the firm should submit Phase IV clinical trial protocol before the committee for further review.
Biological Division			
7.	4-25/Roche/PAC-R-Atezolizumab/2022-BD Atezolizumab Injection 1200mg/20ml and 840mg/14ml Vials	M/s. Roche Products India Pvt. Ltd.	The firm presented proposal for approval of additional indication of the drug. After detailed deliberation, the committee recommended for grant of approval of proposed indication in line with USFDA approval as below: "Atezolizumab, as a single agent, as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II to IIIA non small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on ≥ 1% of tumor cells".
8.	BIO/CT21/BO/2022/30917 Rituximab	M/s. Zydus Life Science Pvt. ltd	The proposal of the firm to manufacture and market Rituximab in the country based on the results of Phase I (PK-PD) and Phase III clinical trial was deliberated on SEC meeting held on 15.06.2022. In continuation of the SEC recommendation dated 15.06.2022 the proposal of the firm was redeliberated for review wherein the firm presented their justification further for the clinical trial results and the proposed Phase IV clinical trial. After detailed deliberation, the committee reiterated the recommendation for grant of manufacture and market subject to the condition that the firm should conduct Phase IV clinical trial in not less than 231 subjects in the country. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of marketing approval and advised that the

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			firm should submit statistical analysis report alongwith certificates by statistician.
9.	BIO/CT04/FF/2022/ 31172 Pertuzumab 420mg concentrate for solution for infusion	M/s. Accutest Research Laboratories (I) Pvt. Ltd.	The firm presented proposal for conduct of Phase I study with the drug. After detailed deliberation, the committee recommended that, the firm should further submit clarification with respect to following: 1. Clear objective for conduct of proposed study and purpose of conducting study in healthy subjects. 2. Facility set-up for conduct of such study and details of similar such studies conducted by the study centre. Also, Medical oncologist should be included in proposed study. Accordingly, the firm should submit response along with revised protocol for further deliberation by the committee.
10.	BIO/IMP/22/000043 Nivolumab	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented proposal for grant of approval for additional strength (240 mg/24ml) and flat dose-based dosing regimen for Nivolumab in approved indications. After detailed deliberation, the committee recommended for grant of permission for additional strength and flat dose-based dosing regimen as presented.
SND Division			
11.	SND/IMP/22/000046 Abemaciclib Tablets 50mg, 100mg 150mg & 200mg	M/s. Eli Lilly	The firm presented their proposal of import and marketing permission of Abemaciclib Tablets 50mg, 100mg, 150mg and 200mg for additional indication "Early Breast Cancer: Ramiven® in combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, node positive early breast cancer at high risk of recurrence. In pre or postmenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone agonist" with Indian population data of Global Clinical Trials conducted before the committee.

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			The committee noted that the proposed indication is similar with EU approved indication. After detailed deliberation, the committee recommended for grant of import and marketing permission of Abemaciclib Tablets 50mg, 100mg, 150mg and 200mg for additional indication as mentioned above.
GCT Division			
12.	CT/44/21 Online Submission (14540) Atezolizumab & Trastuzumab	M/s. Roche	The firm didn't turn up for presentation.
13.	CT/54/20 Online Submission (12774) Trastuzumab Deruxtecan	M/s. AstraZeneca	In light of earlier SEC recommendation dated 23/06/2022, the applicant presented detailed justification for protocol amendment version 3.0 dated 27/07/2021, before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment version 3.0 dated 27/07/2021.
14.	CT/118/20 Online Submission (19919) Darolutamide	M/s. Bayer Pharmaceutical	The firm presented clinical trial protocol amendment version 2.0 dated 28 June 2022 before the committee. After detailed deliberation, the committee recommended that the firm should submit details of applications and their approvals in chronological order regarding change in sample size, as applicable globally.
15.	CT/21/21 Online Submission (15430) OQL011	M/s. CBCC	The firm presented clinical trial protocol amendment version 10.1 dated 19 July 2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
16.	CT/37/20 Online Submission (31619) NBTXR3 & Cetuximab	M/s. PRA	The applicant has presented Phase III clinical trial protocol no. NANORAY-312 before the committee. The applicant informed that Phase I clinical trial study is on-going in USA, no Phase II clinical trial was carried out anywhere and on the basis of ongoing

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			Phase I trial data, USFDA granted permission to conduct the proposed Phase III clinical trial without conduct of Phase II clinical trial. After detailed deliberation, the committee recommended that the applicant should submit Phase I data of on-going 54 subjects along with USFDA submission letter for Phase I data for further consideration. As the proposed Phase III trial will be conducted in 500 subjects including 19 subjects from India, the committee suggested that the applicant may include more subjects from India.
17.	CT/97/21 Online Submission (18066) Amivantamab & Lazertinib	M/s. J&J	The firm presented clinical trial protocol amendment version 2, dated 24 March 2022 before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.