Recommendations of the SEC (Oncology & Haematology) made in its 152nd meeting held on 11.07.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/23/000037 Tenalisib Tablets 400mg	M/s. Syngene International Limited	The firm presented the Phase II protocol of Tenalisib tablets 400mg in patients with metastatic triple negative breast cancer (TNBC). The committee reviewed the data submitted by the firm in details and noticed that there is only single patient data of Phase I for the indication of TNBC to consider for the proposed Phase II study. The committee after detailed deliberation opined that the firm needs to submit adequate Phase I data for further review by the committee.
2.	ND/IMP/22/000015 Selpercatinib 40 mg & 80 mg	M/s. Eli-Lilly	The firm presented its proposal to waive off Phase IV clinical trial in the country before the committee. The committee deliberated the ongoing Phase III global clinical trial data and found that out of 48 screened patients only 11 were enrolled. The committee felt that Phase III Clinical trial data is not sufficient on Indian patients on the proposed indications hence the request of firm to consider for Phase IV waiver cannot be considered for approval at this stage. Hence, the committee did not recommend for waiver of Phase IV study for the applied indications.
3.	ND/IMP/19/000039 Dacomitinib Tablets 15mg, 30mg & 45mg	M/s. Pfizer Product India Pvt. Ltd.	The firm presented the Phase IV Clinical trial report. The committee reviewed in detail the Phase IV study report and noticed that there were 9 deaths reported by the firm. However, details of these deaths were not presented for review to the committee by the firm. The Committee recommended that the firm should submit the details including causality analysis of the SAEs of death for further evaluation by the committee.
4.	12-01/23-DC (Pt-90) 5-Flurouracil Injection	AIIMS, Raipur	The proposal was deferred for next SEC meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	ND/MA/23/000094 Erdafitinib Tablets 3mg, 4mg and 5mg	M/s. Natco Pharma Limited	The proposal was deferred for next SEC meeting.
6.	12-01/23-DC(Pt-86) Goserelin Acetate Depot Injection 10.8mg (Zoladex)	M/s. AstraZeneca Pharma India Limited	The proposal was deferred for next SEC meeting.
7.	ND/MA/22/000144 Relugolix Tablets 120mg	M/s Zydus Lifesciences Ltd.	The proposal was deferred for next SEC meeting.
Biological Division			
8.	BIO/CT04/FF/2023/ 36803 Denosumab Injection 120 mg/1.7 mL	M/s. Hetero Biopharma Limited	The proposal was deferred for next SEC meeting.
9.	BIO/CT18/FF/2022/ 34156 Nivolumab 10 mg/ml concentrate for solution for infusion (40 mg & 100 mg)	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The proposal was deferred for next SEC meeting.
SND Division			
10.	SND/MA/22/000246 EribulinMesylate solution for injection 2.5 mg in 5ml vial	M/s. Emcure Pharmaceuticals Limited	The firm presented their proposal for additional pack size of EribulinMesylate solution for injection 2.5mg in 5ml vial with rational and dose justification in light of previous recommendation of SEC (Oncology & Haematology) held on 07.10.2022. The committee opined that due to absence of any specific scientific justification in support of the proposed pack size of EribulinMesylate solution for injection the proposal cannot be considered for approval at this stage.
11.	SND/MA/23/000145 Arsenic Trioxide	M/s Cipla Ltd.	The proposal was deferred for next SEC meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Oral Solution 1mg/ml – 5ml (Additional dosage from & Indication)		
12.	SND/MA/23/000150 Bortezomib 2.5mg/ml & Bartezomib 3.5/1.4ml (2.5mg/ml) (Ready to use)	M/s Dr. Reddy's Laboratories Ltd.	The proposal was deferred for next SEC meeting.
GCT Division			
13.	CT/39/23 Online Submission (37172) Serpin PC	M/s. Inventive International	The firm presented their proposal for Phase IIb clinical trial protocol number AP-0103, before the committee. The committee noted that as per inclusion criteria No. 07 of proposed protocol, subjects from another study no AP-0105 may be eligible for the present study. After detailed deliberation, the committee recommended that the applicant should submit the details of Study No- AP -0105 and its approval from India for further consideration.
14.	CT/176/22 Online Submission (34952) Atezolizumab Injection 1200mg/20ml Sorafenib 200 mg Lenvatinib	M/s. Roche	The firm presented the proposal for grant of permission to conduct Phase III clinical trial with study protocol no. MO42541 version 3.0 dated 21-July-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that during screening visit Quantiferone-TB Gold test should be carried out and in subsequent visits trial subjects should be further assessed for TB.
15.	CT/23/23 Online Submission (36506) Pertuzumab	M/s. CliniRx	The firm presented proposal for Phase III clinical trial protocol number BCD-178-2/PREFER, before the committee. After detailed deliberation, the committee recommended for grant permission to conduct the study.
16.	CT/07/23 Online Submission (35658)	M/s. CBCC	In light of earlier SEC held on 27-04-2023, the applicant presented supportive preclinical data and clarified the proposed study design before the committee.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	HT-6184 (2mg Caps)		After detailed deliberation, the committee recommended for grant of permission to conduct the study subject with condition that Govt academic institutes/sites should be added and PI/Co-I at each site should be hematologist.
17.	CT/36/22 Online Submission (21074) Selpercatinib	M/s. Eli Lilly	The proposal was deferred for next SEC meeting.
18.	CT/46/23 Online Submission (37340) Elrantamab + Daratumumab + Lenalidomide	M/s. Pfizer	The proposal was deferred for next SEC meeting.
19.	CT/44/23 Online Submission (37301) Pozelimab& Cemdisiran	M/s. Parexel	The proposal was deferred for next SEC meeting.
20.	CT/40/17 Online Submission (25623) Abemaciclib	M/s. Eli Lilly	The proposal was deferred for next SEC meeting.
21.	CT/132/20 Online Submission (21879) BP01(Bevacizumab)	M/s. Curateq	The proposal was deferred for next SEC meeting.
22.	CT/13/23 Online Submission (35992) PZN-128	M/s. GCT Pharma Research	In light of earlier SEC recommendations of SEC dated 28.03.2023 & 29.03.2023 and 30.05.2023, the firm presented the proposal for grant of permission to conduct Phase III clinical trial after revising the study protocol before the committee. After the detailed deliberation, the committee recommended for grant of permission to conduct the study.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Device Division			
23.	CI/MD/2022/77493 Cervical Cancer Screening Device (CerviScan)	M/s. Sascan Meditech Pvt. Ltd	The proposal was deferred for next SEC meeting.
24.	CI/MD/2023/86807 Hydrating oral Patch	M/s. Bylin Meditech Pvt. Ltd.	In light of earlier SEC recommendation dated 11.05.2023, the firm presented their revised pivotal clinical investigation protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the pivotal clinical investigation on Indian population in the country.