Recommendations of the SEC (Oncology & Haematology) made in its 145th meeting held on 28.03.2023 & 29.03.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/22/000063 Asciminib FCT 20mg & 40mg	M/s. Novartis Health Care Pvt. Ltd.	The firm presented its proposal for import and marketing of the drug Asciminib FC Tablets 20mg and 40mg along with justification for local Phase III clinical trial waiver before the committee. The committee noted that Asciminib tablet formulation is approved in many countries including the European Union, Singapore, Canada, Japan etc. After detailed deliberation, the committee recommended that the drug is falling under the category of orphan drug and indicated for the treatment of patients with Philadelphia chromosome-positive Chronic Myeloid Leukemia (Ph+ CML) in chronic phase (CP) previously treated with two or more Tyrosine kinase inhibitors (THIs) and Ph+ CML in CP with the T315I mutation which is serious and life threatening disease and there is an unmet medical need in the country and accordingly the committee recommended for grant of permission to import and marketing of Asciminib FC Tablets 20mg and 40mg . 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 further review by the committee.
2.	ND/CT/21/000081 Capmatinib 150 mg & 200 mg Tablets	M/s. Novartis Healthcare	The firm presented its proposal for amendment of Phase IV clinical trial protocol no- CINC280AIN01, version 2.0 dated 03-Jan-2023 of already approved Phase IV clinical trial of Capmatinib 150mg & 200mg tablet. After detailed deliberation, the committee recommended for the approval of the proposed protocol amendment.
3.	ND/MA/23/000026 Relugolix tablets 120mg	M/s. Sun Pharma	The firm presented its proposal for manufacture and marketing of the drug Relugolix 120mg tablets indicated for treatment of adult patients with advanced prostate cancer along with BE study report and justification for local clinical trial waiver. The firm presented the results of

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			innovator's Phase III multinational clinical trial conducted in other countries. The committee noted that the drug is approved in US and 27 EU member states. The committee opined that there is an unmet medical need in the country. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug with waiver of local Phase III clinical trial in the country with the condition that the firm should conduct Phase IV clinical trial for which the protocol should be submitted within 3 months of approval of the drug for review by the committee.
Biological Division			
4.	BIO/CT21/FF/2023/36021 Bevacizumab 100mg & 400mg	M/s. Reliance Life Sciences Pvt. Ltd	The firm presented the proposal for approval of proposed additional indications before the committee. Hepatocellular carcinoma: Bevacizumab in combination with Atezolizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy. After detailed deliberation, the committee recommended that the firm should submit safety and efficacy data for the proposed additional indication in Indian patients.
5.	BIO/CT04/FF/2022/31172 Pertuzumab 420mg/14mLvial	M/s. Accutest Research Laboratories (I) Pvt. Ltd.	In light of earlier SEC recommendation dated 08.09.2022 & 13.09.2022, the committee presented the revised PK/PD protocol version 03 dated 30-Dec-22. After detailed deliberation, the committee recommended for conduct of the study as per the presented protocol with the following changes- 1. The Principal investigator should be MD in Pharmacology and Co-investigator should be specialist in Oncology. Accordingly, the firm should submit revised protocol to CDSCO.
6.	BIO/IMP/22/000075 Tremelimumab concentrate for solution for infusion	M/s. Astra Zeneca	The firm presented the proposal for import & marketing of the drug Tremelimumab 20mg/mL Concentrate for Solution for Infusion. The drug in combination with Durvalumab is indicated for the treatment of patients with Unresectable Hepatocellular Carcinoma (uHCC). The committee noted that the drug is

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			approved in EU, USA and Japan. The firm presented the results of global clinical trials data of Phase III study (HIMALAYA) in which India is also part of the clinical trial and data from supportive Phase I/II study. After detailed deliberation, the committee recommended for grant of permission to import and market the drug for the treatment of patients with Unresectable Hepatocellular Carcinoma (uHCC) with the condition that the firm should submit PMS data through PSUR to CDSCO regularly.
7.	4-10/Dr. Reddy's/PAC-R-Bevacizumab/2021-BD (Pt-1) Bevacizumab 100mg & 400mg	M/s. DRL	The firm presented the proposal for update in package insert. After detailed deliberation, the committee recommended for update in proposed package insert (Ref no PI-BZ-C-04-IN-04-11/22) in line with innovator Package insert.
8.	BIO/IMP/23/000003 Enfortumabvedotin 20 mg & 30 mg	M/s. Astellas Pharma India Pvt. Ltd.	The firm did not turn up for presentation.
SND Division			
9.	SND/MA/23/000028 Abiraterone Acetate oral suspension 1000mg/5ml	M/s. BDR Pharmaceuticals Int. Pvt. Ltd.	The firm presented the proposal for manufacturing& marketing of the drug Abiraterone Acetate oral suspension 1000mg/5ml. Firm presented the therapeutic rationale and justification for the proposed dosage form and strength along with the BE study protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study.
10.	SND/IMP/22/000042 Ruxolitinib tablets 5 mg, 10mg, 15mg, and 20mg	M/s. Novartis Healthcare Pvt. Ltd	The firm did not turn up for presentation.
11.	SND/MA/22/000313 Micronized Purified Flavanoid Fraction 500mg Tablets	M/s Servier India Pvt. Ltd.	In light of earlier SEC recommendation dated 09.02.2023, the firm presented the proposal of manufacture and marketing permission of Purified Flavonoid Fraction 500mg Tablets (Additional Strength) for the indication as: 1. "Treatment of symptoms related to venolymphatic insufficiency (heavy legs,

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			pain, restless leg syndrome)". 2. "Treatment of functional symptoms related to hemorrhoidal attack" alongwith justification of clinical trial waiver, details of global clinical trial data and approval status of the applied drug product in other countries with proposed indications, before the committee. After detailed deliberation, the committee recommended that the firm should submit detailed data regarding pathophysiology of proposed indication alongwith possible mechanism of action of the drug product with supportive evidence to CDSCO for further review by the committee. The committee also recommended that the proposal should be presented in presence of general or vascular surgeon or gastrointestinal surgeon in the next SEC (Oncology & Haematology) meeting.
GCT Division			
12.	CT/184/22 Online Submission (35348) Pembrolizumab	M/s. MSD	The firm presented its proposal for Phase III clinical study protocol number: MK3475-905, version 08 dated 01-Nov-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical study subject to the condition that the firm should increase subjects from 25 to 40 subjects & include more sites from India.
13.	CT/155/22 Online Submission (35004) MK-7684 + Pembrolizumab	M/s. MSD	The firm presented its proposal for Phase III clinical study protocol number: MK7684A, version 010-00 dated 15-Sept-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical study subject to the condition that the firm should increase subjects from 50 to 80 subjects & include more sites from India.
14.	CT/105/22 Online Submission (33987) Phesgo + Giredestrant	M/s. Roche	The firm presented its proposal for Phase III clinical study protocol number: WO43571, Version 2, dated 19 May 2022 before the committee. After detailed deliberation, the committee recommended that the firm should submit the summary of changes from protocol

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			version 1.0 to protocol version 2.0 to CDSCO for re-deliberation before the committee.
15.	CT/97/22 Online Submission (33424) Pertuzumab & Trastuzumab	M/s. Roche	The firm presented the Phase IIIB clinical study protocol number: MO43110, Version 1.0, dated 02-Feb-2022 before the committee. After detailed deliberation, the committee again noted that the firm has not submitted the toxicity data of proposed fixed dose combination product and recommended that the firm should submit all previous approval of the proposed combination product to CDSCO for reconsideration by the committee.
16.	CT/92/22 Online Submission (33698) Teclistamab + Daratumab + Lenalidomide	M/s. J&J	The firm presented Phase III clinical trial protocol no. 6400795MMY3005 version no. amendment no. 1 dated 24-June-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the proposed trial with the following conditions: 1. The applicant should submit safety data of 30 subjects from safety run in period along with the IDMC recommendations. 2. All SAEs including death (i.e. due to PD) irrespective of its causality assessment should be reported to CDSCO as per provision of NDCT Rules 2019.
17.	CT/151/22 Online Submission (34938) KRC-01	M/s. Prorelix Services	The proposal will be deliberated in next meeting in presence of Radio-oncologist.
18.	CT/104/22 Online Submission (23457) Mim8	M/s. Novo Nordisk	In light of CT NOC condition no. 1 i.e. 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, the applicant has presented its proposal for amendment in above CTNOC condition, before the committee. After detailed deliberation, the committee recommended to amend the CTNOC condition as- the applicant should submit interim efficacy and safety data of first part

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			of the study for further review by the committee.
19.	CT/117/21 Online Submission (22130) Datopotamab	M/s. AstraZeneca	The proposal was deferred for the next meeting.
20.	CT/110/21 Online Submission (20852) Oral Asciminib	M/s. Novartis	The proposal was deferred for the next meeting.
21.	CT/132/20 Online Submission (21879) Bevacizumab	M/s. Curateq	The firm presented protocol number: CR187-18, protocol amendment version 1.0 dated 02.11.2021 before the committee. After detailed deliberation, the committee recommended that the firm should submit proper rationale for enrollment of 80% sample size from India. The applicant is also required to submit regulatory approval letter/status from other participating countries for proposed protocol amendment for further review by the committee.
22.	CT/49/17 Online Submission (20884) Lorlatinib (PF 06463922)	M/s. Pfizer	The firm presented the protocol amendment 6 dated 21 March 2022; study protocol no. B7461006 before the committee. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
23.	CT/17/21 Online Submission (22781) Ruxolitinib	M/s. Novartis	The proposal was deferred for the next meeting.
24.	CT/44/21 Online Submission (23581) Atezolizumab	M/s. Roche	The proposal was deferred for next SEC meeting on the request of Applicant.
25.	CT/75/21 Online Submission (23014)	M/s. Pfizer	The firm presented the protocol amendment 2 dated 01 Dec 2022; study protocol no. B7841007 before the committee. After detailed deliberation, the committee

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	Marstacimab		recommended that the firm should submit complete details of all the ongoing and completed trials conducted on the IMP worldwide. The proposal is to be redeliberated.
26.	CT/100/23 Online Submission (33813) JDQ443	M/s. Novartis	The proposal was deferred for the next meeting.
27.	CT/95/19 Online Submission (18331) Selpercatinibz	M/s. Eli Lilly	The firm did not turn up for the presentation.
28.	CT/89/21 Online Submission (22688) Lutetium (177Lu) Edotreotide	M/s. PSI CRO	The proposal was deferred for the next meeting.
29.	CT/159/22 Online Submission (35059) ARV-471 (PF-07850327)	M/s. Pfizer	The firm presented the Phase III clinical trial, study protocol number: C4891001, amendment 1 dated 25-Oct-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.
30.	CT/47/20 Online Submission (22750) Durvalumab	M/s.AstraZeneca	The proposal was deferred for the next meeting.
31.	CT/13/23 Online Submission (35992) PZN-128	M/s. GCT Pharma Research	The firm presented the Phase III clinical trial; study protocol number: PZN-128, version-1.0 dated 13-Dec-2022 before the committee. After detailed deliberation, the committee recommended to revise the study protocol as below and to be redeliberated- 1. The dose schedule of study drug should be clearly mentioned. 2. Use of glucocorticosteroids should

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			be excluded. 3. Duration for evaluation of primary efficacy end point should be atleast for one year.