Recommendations of the SEC (Oncology & Hematology) made in its 113th meeting held on 07.10.2021 & 08.10.2021 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT04/FF/2021/28090 Capmatinib film-coated tablet	M/s Novartis Healthcare Pvt. Ltd	The firm presented their proposal of phase-IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the phase-IV clinical trial as per the protocol presented.
2.	12-66/14-DC (Pt-Active Surveillance) Nintedanib Soft Gelatin Capsules 100 , 150 mg	M/s Boeringer Ingelheim	The firm presented their proposal of amendment in active surveillance study protocol with request for one year extension for recruitment of patients before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment as per protocol presented and also opined that, the firm should submit the complete report before the committee by end of Dec 2022 for further consideration.
3.	ND/IMP/21/000014 Romidepsin for Injection 10mg/Vial	M/s MSN Lab Ltd	The firm presented their proposal for approval of the BA protocol before the committee. After detailed deliberation, the committee reiterated its earlier recommendation dated 06.01.2021 & 07.01.2021. Accordingly, firm should submit the revised protocol for BA study to be conducted in comparison with innovator product for further review by the committee.
4.	ND/IMP/21/000040 Pralsetinib Capsules	M/s Roche	The firm presented their proposal for import and marketing of the drug Pralsetinib Capsules 100mg along with justification for CT waiver before the committee. The committee opined that proposed indication is a very rare condition and there is unmet medical need for the drug 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 firm should conduct a Phase-IV clinical trial for which protocol should be submitted within 3 months of approval of

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			the drug for review by the committee. The drug should be sold by retail only under the prescription of Oncologist.
5.	ND/CT18/FF/2021/27836 Fosnetupitant and Palonosetron 235 mg/0.25 mg concentrate for solution for infusion (Akynzeo® IV)	M/s Glenmark Pharmaceuticals Ltd.	The firm presented their proposal for import and marketing of the drug Fosnetupitant and Palonosetron 235 mg/0.25 mg concentrate for solution for infusion (Akynzeo® IV) along with CT waiver before the committee. The committee observed that the drug is intended for use in patients who are not able to take oral anti emetic medicines and this is an unmet medical need for the drug in the country. After detailed deliberation, the committee recommended for grant of permission to import and market of the drug with local clinical trial waiver for the indication as approved in USA subject to the condition that the 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. The drug should be sold by retail only under the prescription of Oncologist.
6.	12-01/21-DC (PU-009) Carfilzomib Injection 30/60 mg	Ms Amgen Technology Pvt Ltd	The firm presented their proposal for updating the prescribing information of the drug before the committee. After detailed deliberation, the committee recommended for grant of approval of updated prescribing information of Carfilzomib Injection 30/60 mg as presented by the firm.
7.	ND/MA/19/000077 Tegafur+Gimeracil+ Oteracil capsules (15mg/4.35mg/11.8mg & 20mg/5.8mg/15.8mg)	M/s BDR Pharmaceuticals International Pvt. Ltd.	The firm presented their proposal along with BE report before the committee. After detailed deliberation, the committee opined for redeliberation of proposal along with all the details of sites from where the patients were referred, along with individual patient data with Gastrectomy details and other medical history.
Biological Division			
8.	BIO/CT/18/000047 Pembrolizum	M/s. MSD Pharmaceuticals Pvt. Ltd.	The firm presented their proposal for amendment to already approved CT protocol. After detailed deliberation, the committee recommended for grant of approval for the proposed protocol amendments.

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9.	BIO/CT/20/000195 Filgrastim	M/s. IQVIA RDS (India Pvt. Ltd.)	The firm presented their proposal for amendments to already approved CT protocol. After detailed deliberation the committee recommended for grant of approval for the proposed protocol amendments.
10.	BIO/CT/18/FF/2021/27039 Nivolumab	M/s. BMS	The firm didn't turn up for the presentation.
11.	04-05/Roche/PAC-R-Atezolizumab/2021-BD Atezolizumab	M/s. Roche Product (India) Pvt. Ltd	The firm presented the proposal for addition of new indication for Atezolizumab 1200 mg/20 ml & 840 mg/14 ml based on the results of a randomized Phase III trial conducted overseas including both squamous and non-squamous NSCLC. The committee noted that the proposed indication is approved in US, Europe, Japan, etc. After detailed deliberation, the committee recommended for grant of approval of Atezolizumab as monotherapy for the first-line treatment of patients of metastatic NSCLC whose tumors have a PD L1 expression ≥ 50 % tumor cells or ≥ 10% tumor infiltrating immune cells and who do not have EGFR or ALK genomic tumor aberrations.
12.	4—76/Novo Nordisk/PAC-R-Catridecacog/2021-BD Catridecacog (rFXII)	M/s. Novo Nordisk	The firm presented the proposal for extension of indication for Catridecacog (Recombinant Coagulation factor XII) based on Post authorization safety study (Non interventional). After detailed deliberation, the committee recommended for grant of approval for extension of indication as treatment of breakthrough bleeding episodes during regular prophylaxis and updation in the posology of the drug.
13.	BIO/MA/21/000057 Bevacizummab	M/s. Cura TeQ	The firm presented the proposal for grant of marketing authorization to Bevacizumab with local phase-III clinical trial waiver. The Committee noted that the firm has not generated safety and efficacy data on the drug in any country. Therefore, after detailed deliberation, the committee did not recommend for grant of marketing authorization for the drug in the country.

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SND Division			
14.	SND/IMP/21/000086 Ibrutinib capsules 140mg	M/s Johnson & Johnson	The firm presented the proposal for additional indication along with the clinical data. The committee noted that the proposed indication is already approved in major/ key countries. After detailed deliberation, the committee recommended for grant of permission for import and market the drug for the additional indication, Marginal Zone Lymphoma (MZL)
15.	SND/IMP/21/000087 Ibrutinib capsules 140mg	M/s Johnson & Johnson	The firm presented the proposal for additional indication along with the clinical data. The committee noted that the proposed indication is already approved in major/ key countries. After detailed deliberation the committee recommended for grant of permission for the drug for additional indication i.e. chronic Graft Versus Host Disease (cGVHD)
16.	SND/MA/21/000323 Tranexamic Acid Spray 10% w/v	M/s. Shilpa Medicare	In light of earlier recommendation of the committee dated 06.08.2021 & 10.08.2021 the firm presented their proposal with issues of specific indication and CT waiver before the committee. After detailed deliberation the committee recommended for conducting Phase III Clinical trial and the firm should submit well designed CT protocol for further evaluation by the committee.
GCT Division			
17.	CT/29/18 Osimertinib	M/s. AstraZeneca	The firm presented their proposed protocol amendment before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment version 3.0 dated 3rd February 2021.
18.	CT/10/18 Atezolizumab	M/s. Roche	The firm presented their proposed protocol amendment before the committee. After detailed deliberation, the committee opined that the firm should give justification for allowing the use of immunosuppressant in subset of patients for further review by the committee.

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19.	CT/99/20 Trastuzumab Deruxtecan	M/s. AstraZeneca	The firm presented their proposed protocol amendment before the committee. After detailed deliberation the committee opined that the firm should submit statistical justification for sample size, study design for further review by the committee.
20.	CT/64/19 Ribociclib plus Goserelin acetate	M/s. Novartis	The firm presented their proposed protocol amendment before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment version 2.0 dated 04.03.2021
21.	CT/79/20 Amivantamab	M/s. J&J	The firm presented their proposed protocol amendment before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment version 1.0 dated 20 May 2021.
22.	CT/75/21 Online Marstacimab prophylaxis	M/s. Pfizer	The firm has presented their proposal for Phase III Clinical Study before the committee. **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-** To evaluate the long-term safety, tolerability, and efficacy of marstacimab prophylaxis in participants with severe hemophilia a and b with or without inhibitors **Unmet medical need in the country-** The test drug is used in severe Hemophilia a and b with or without inhibitors. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical study**.**

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23.	CT/61/19 Concizumab prophylaxis	M/s. Novo-Nordisk	The firm presented their proposed protocol amendment before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment version 7.0 dated 18 June 2021.
24.	CT/87/21 Online Giredestrant	M/s ROCHE	The firm presented their proposal for phase III Clinical trial before the committee. **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-** To demonstrate superiority of giredestrant over the control treatment. **Unmet medical need in the country-** The test drug is used for patient with estrogen receptor–positive, her2-negative early breast cancer. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III Clinical Study.
25.	CT/95/19 Online Cabozantinib or Vendetanib	M/s Eli-lilly	The firm presented their protocol amendment before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol J2G-MC-JZJB(d) dated 15 Feb-2021.
BA/BE Division			
26.	12-09/2021/BA-BE/Misc-21/DC Lenvatinib 24 mg Capsules	M/s. ClinSync Clinical Research Private Limited, Hyderabad-500050	The firm presented the BE study protocol for Lenvatinib 24 mg Capsules. After detailed deliberation, since the current application is for export registration purpose, the committee recommended that permission for the proposed BE study may be granted with condition to select Innovator product as reference product

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			instead of their own product marketed in India as a reference product.