Recommendations of the SEC (Oncology & Haematology) made in its 161st meeting held on 09.11.2023 & 10.11.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000155 Ferric Maltol Capsules 30mg	M/s. Precise Biopharma Pvt. Ltd.	The proposal was deferred by the committee for the want of more information/data by the firm.
Biological Division			
2.	BIO/CT21/FF/2023/36021 Bevacizumab 100mg and 400mg	M/s. Reliance Life Sciences	In light of earlier SEC recommendations dated 28.03.2023 and 29.03.2023, the firm presented the justification for consideration of local clinical trial waiver for approval of the additional indication- "Hepatocellular Carcinoma (HCC) 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 for approval of proposed additional indication with local clinical trial waiver with condition to conduct a Phase IV study to establish safety and effectiveness of Bevacizumab in combination with atezolizumab. Accordingly, the firm should submit Phase IV protocol to CDSCO within 3 months of approval of additional indication for further evaluation by the committee.
3.	BIO/CT04/FF/2023/38332 Romiplostim 250mcg	M/s. Levim Biotech	The firm presented the proposal to conduct Phase III clinical study titled "Randomized, double-blind, parallel arm, comparative clinical study to test the non-inferiority of biosimilar Romiplostim with Nplate in patients with ITP" vide Protocol no. LBL-CT-20-003, Version 2.0for the drug Romiplostim 250 mcg for injection (r-DNA). After detailed deliberation, the committee recommended for inclusion of PK sampling and analysis in the subset of population on higher doses in the clinical study protocol. Accordingly, the firm should submit revised protocol to CDSCO for further evaluation by the committee.

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4.	BIO/CT21/BO/2023/38200 Bevacizumab 100mg and 400mg	M/s. Enzene	The firm presented the proposal for grant of permission for extrapolation of additional indications of the drug Bevacizumab Injection 100mg/4mL and 400mg/16mL in line with the indications approved for the innovator product. After detailed deliberation, the committee recommended that the firm should submit first PSUR data of the drug Bevacizumab Injection 100mg/4mL and 400mg/16mL for evaluation and further consideration by the committee.
5.	BIO/CT21/BO/2023/38835 Trastuzumab 150mg and 420mg	M/s. CurateQ	The firm presented the proposal to manufacture and market Trastuzumab 150mg and 420mglyophilized powder in single dose vial. The firm presented the study results from the comparative PK/PD and immunogenicity study conducted in healthy volunteers with the study drug in New Zealand. The firm also presented the efficacy and safety data of the study drug (except the immunogenicity data) from the Phase III trial conducted in India. After detailed deliberation, the committee recommended that the firm should submit immunogenicity data of patients in Phase-III clinical trial in India for further review by the committee for grant of marketing authorization for domestic market. However, the committee recommended for grant of permission of marketing authorization for the export market for the proposed indications based on the presented clinical data.
6.	BIO/CT18/FF/2023/36308 Nonacogalfa (Factor IX)	M/s. Pfizer	In light of earlier SEC recommendation dated 24.03.2022, the firm presented the proposal for alignment of approved indication for the drug Nonacogalfa (recombinant human coagulation factor IX)as per the USPI indication i.e. “Indicated in adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the

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			frequency of bleeding episodes Limitation of Use: Nonacogalfa (recombinant coagulation factor IX) is not indicated for induction of immune tolerance in patients with hemophilia B. After detailed deliberation, the committee recommended for approval of the proposed indication aligned with US PI indication.
7.	BIO/CT04/FF/2023/38062 Cetuximab Injection	M/s. Enzene	The firm presented the proposal to conduct Phase IV clinical trial titled "A prospective, multicenter, Phase IV study to evaluate the safety and efficacy of Biosimilar cetuximab either alone or in combination with investigator choice chemotherapy/ radiotherapy in patients with locoregionally advanced or recurrent locoregional or metastatic squamous cell carcinoma of the head and neck (SCCHN)" vide Protocol No. ALK30/ENZ124-CET2 Version 1.0/01-Jun-2023. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per the protocol presented by the firm.
8.	BIO/CT18/FF/2022/35249 Ipilimumab 5mg/ml Concentrate for solution for infusion	M/s. BMS	In light of earlier SEC recommendation dated 10.10.2023, the firm presented their proposal for waiver of Phase IV trial condition for the additional indication as follows "Ipilimumab, in combination with nivolumab is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC)". After detailed deliberation, the committee noted that there is an ongoing Phase IV study with the combination of Nivolumab and Ipilimumab in patients with previously untreated Advanced Renal Cell Carcinoma and accordingly the committee recommended that the firm should present the safety data in Indian patients upon completion of the study for review by the committee.
9.	BIO/CT18/FF/2022/35291	M/s. BMS	In light of earlier SEC recommendation dated 10.10.2023, the firm presented their

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	Nivolumab 10mg/ml concentrate for solution for infusion 40mg &100mg		proposal for waiver of Phase IV trial condition for the following additional indication- 1)Nivolumab in Combination with Ipilimumab for the treatment of Advanced or metastatic esophageal squamous cell carcinoma (ESCC) 2) Nivolumab in Combination with Fluoropyrimidine- and Platinum-containing Chemotherapy for the treatment of Advanced or metastatic esophageal squamous cell carcinoma (ESCC) 3) Nivolumab for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC. The firm presented the data for safety profile of Nivolumab in Indian patients (Phase-IV and PSURs) and requested for the waiver of Phase-IV trial stating that "the drug should be considered as orphan drug for the indication ESCC and UC in Indian scenario". After detailed deliberation, the committee noted that a Phase IV study is ongoing with the combination of Nivolumab and Ipilimumab in patients with previously untreated Advanced Renal Cell Carcinoma and accordingly the firm should present the safety data in Indian patients upon completion of the Phase-IV study for review by the committee for consideration of waiver of Phase-IV clinical trial for the Indication no. (1). Further, the committee noted the safety and efficacy results of Nivolumab in combination with chemotherapy and recommended for the grant of Phase IV trial waiver for the indication no. (2) and (3).
10.	BIO/IMP/22/00008 Nivolumab 10mg/ml concentrate for solution for infusion	M/s. BMS	In light of earlier SEC recommendation dated 25.07.2023, the firm presented their proposal for waiver of Phase IV trial condition stipulated in the permission issued for the additional indication of "first-line treatment of patients with advanced Renal cell carcinoma (RCC) in

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			combination with Cabozantinib". The firm presented the data for safety profile of Nivolumab in Indian patients (Phase IV and PSUR data) and requested for the waiver of Phase-IV trial stating that "the drug should be considered as orphan drug for the indication of advanced Renal Cell Carcinoma in India". After detailed deliberation, the committee recommended for Phase IV trial waiver for the proposed additional indication.
11.	BIO/CT04/FF/2023/37705 Denosumab 120mg/mL	M/s. Biocon	The firm presented the protocol for the conduct of PK/PD study titled "A Randomized, Double-blind, Two-arm, Single-dose, Parallel Group Study to Compare the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Bmab 1000 and EU-Approved Xgeva® in Normal Healthy Male Volunteers" vide Protocol No. BIO-BM1000-103, V1.0 dated 16.05.2023. After detailed deliberation, the committee recommended for following changes in the protocol- 1. The firm should include adequate laboratory tests to exclude the diseases specified in the exclusion criteria. 2. The protocol should specify the screening tests to rule out osteoporosis. 3. The number of healthy volunteer groups/cohorts per trial arm proposed to be recruited for the study shall be specified. 4. The trial monitoring report by the sponsor shall be submitted to CDSCO on quarterly basis. 5. The safety follow-up parameters as part of the protocol until week 36 shall be specified and adverse events to be reported to CDSCO. Accordingly, the revised protocol shall be submitted to CDSCO for further evaluation.
SND Division			
12.	SND/MA/23/000271 Hydroxyurea Suspension 100mg/ml	M/s. Pure & Cure Healthcare Private Limited	The firm presented their proposal for grant of manufacture and marketing of Hydroxyurea Oral Suspension 100mg/ml along with justification for waiver of

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			Local clinical trial and Bioequivalence study before the Committee. During the presentation, the firm informed that the similar drug Hydroxyurea/hydroxycarbamide 100 mg/ml oral solution is approved and available internationally in Austria, Estonia, Ireland, Lithuania, Poland, United Kingdom (MHRA), Scotland. They also informed that the Hydroxyurea Oral formulation is also included in National Sickle Cell Anaemia Elimination Mission (NSCAEM), Govt. of India. The committee noted that Hydroxyurea Oral Suspension 100mg/ml is indicated for rare disease & serious/life threatening condition and there is an unmet medical need in the country. The drug falls under BCS I category. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Hydroxyurea Oral Suspension 100mg/ml with waiver of Local clinical trial and Bioequivalence study subject to condition that firm should conduct active Phase IV clinical trial and the patients are required to monitor on regular basis for clinical and blood parameter. In addition to above, the firm should fulfill the requirement of CMC data. Accordingly, the firm should submit active Phase IV clinical trial study protocol as earliest or within 01 months to CDSCO from date of approval of the product for further review by the committee.
GCT Division			
13.	CT/103/20 Online Submission (27728) Osimertinib	M/s. AstraZeneca	The firm has presented Protocol amendment version 3.0 dated 10 Jan 2023 Protocol no. D516AC00001. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.

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14.	CT/121/20 Online Submission (27782) NNC0365-3769 / Mim8	M/s. Novo Nordisk	The firm presented protocol amendment version 11.0 dated 12.May.2023 protocol No. NN7769-4514. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm with following conditions: 1. The secondary endpoint should include the number of patients zero bleed. 2. In the inclusion criteria patient's haemophilia A inhibitor level should be tested within 4 weeks of inclusion and inhibitor level should be more than 5 bethesda units.
15.	CT/104/21 Online Submission (28233) LY3484356	M/s. Eli Lilly	The firm did not turn up for presentation.
16.	CT/102/23 Online Submission (39131) Belantamab Mafodotin (GSK2857916) for Injection 100mg	M/s. GSK Pharma	During presentation the firm admitted to the expert committee that they have not submitted earlier phase trials of this molecule to CDSCO. So, the committee recommended that the firm should submit the study data to CDSCO and after that it will be deliberated in the SEC.
17.	CT/91/23 Online Submission (38692) NNC0365-3769 B (Mim8)	M/s. Novo Nordisk	The firm presented Phase IIIb clinical trial protocol No. NN769-4532. After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
18.	CT/39/22 Online Submission (27983) JDQ443	M/s. Novartis	The firm presented protocol amendment version 3.0 dated 5.June 2023 protocol No. CJDQ443B12301. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
19.	CT/164/21 Online Submission (27254) Zanidatamab (ZW25) Tislelizumab (BGB-A317)	M/s. PPD	The firm presented protocol amendment version 3.0 dated 07 Feb 2023 protocol No. ZWI-ZW25-301. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.

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BA/BE Division			
20.	File No. 12-09/2023/BA-BE/MISC-28/DC (BABE/CT05/FF/2023/38845) Lenalidomide 5mg/ml Oral Solution	M/s. Cliantha Research Limited, Ahmedabad.	The firm presented their proposal along with the Protocol of the BE Study for Export Purpose. After detailed deliberation, the committee recommended for grant of BE permission for Export purpose only with condition to provide adequate / satisfactory documentary evidences w.r.t. the potential carcinogenicity of Lenalidomide in healthy volunteers for review before grant of the permission.