Recommendations of the SEC (Oncology & Haematology) made in its 137th meeting held on 25.11.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000104 Ferric Maltol capsules 30mg	M/s. Alkem Labs	The firm presented their proposal for grant of permission to manufacture and market Ferric Maltol Capsules 30 mg along with bioequivalence study protocol (No. CNR-P-022-22, Ver-00, dated: 16 May 2022 and Phase III clinical trial waiver justification before the committee. The committee noted that: • Ferric Maltol Capsules 30 mg is approved in Europe on 18.02.2016 and in USA on 25.07.2019, indicated in adults for the treatment of iron deficiency. • Firm presented detailed published Clinical Overview and Safety Profile Summary of Ferric Maltol capsules 30mg. • Firm presented comparative evaluation data between Ferric Maltol Capsule 30 mg (Mfg. by: Alkem), Batch No.22630002 and Reference Product ACCRUFER (Mfg. By: Shield Therapeutics) Batch No.9014B**.** • Firm presented rationale for Phase III CT waiver that Iron saltsareoften poorly tolerated because of gastrointestinal (GI) toxicity, especially in patients with inflammatory bowel disease (IBD). The parenteral iron products carries the risks such as anaphylaxis, high cost, and the need for administration in a facility that is equipped to respond to severe reactions. Ferricmaltol is a non-salt oral iron formulation composed of iron in the stable ferric (Fe3+) state complexed with a naturally occurring sugar derivative, trimaltol. On intestinal uptake, the complex dissociates and iron is transferred to the iron transport protein, transferrin, and to the storage protein, ferritin, in the

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			systemic circulation. Unlike the iron salts containing ferrous (Fe2+) iron, ferric maltol contains ferric (Fe3+) iron, which has been shown to be less toxic to the GI tract mucosa. Ferric maltol has been shown to increase serum iron parameters, including ferritin and transferrin saturation (TSAT), and correct anemia associated with iron deficiency (IDA). In contrast to ferrous iron salts that dissociate prior to intestinal uptake, the maltol ligand in ferric maltol remains complexed to iron, thereby minimizing the formation of free iron and readily facilitating iron transport across the intestinal wall to the enterocytes in the duodenum and proximal jejunum for uptake. After detailed deliberation, committee opined that there is unmet medical need considering the poor tolerability of Iron salts and the parenteral iron products carries the risks such as anaphylaxis etc. Hence, the committee recommended Phase III clinical trial waiver and grant of permission to conduct bioequivalence study as per the protocol presented. Accordingly, firm should submit the results of bioequivalence study before the committee.
Biological Division			
2.	BIO/IMP/22/000071 Durvalumab 120 mg/2.4 ml & 500 mg/2.4 ml	M/s. Astra Zeneca	The firm presented their proposal for approval of additional indication“locally advanced or metastatic Biliary tract cancer (BTC)”. Firm presented clinical study data generated from global study including data of 24 Indian subjects. The committee noted that, the proposed indication is already approved in USA, Canada, Brazil, South Korea, EU etc. After detailed deliberation, the committee

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			recommended for grant of approval for the proposed additional indication.
3.	BIO/MA/22/000101 Cetuximab 50 mg/ 10 mL, 100mg/ 20 mL, 250 mg/50 mL& 500 mg/100 mL Solution for infusion-Vial	M/s. Enzene Biosciences Ltd.	The firm presented the proposal to manufacture and market Cetuximab based on the comparative Phase III study conducted in India along with the clinical study report. After detailed deliberation, the committee noted the results of the study and recommended for grant of permission to manufacture and market the drug with the condition that the firm should conduct Phase IV clinicaltrial with adequate no. patients as per guidelines. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within three months of manufacturing and marketing approval.
4.	BIO/CT04/FF/2021/25033 Trastuzumab Emtansine 100 mg and 160 mg single-use vials	M/s Zydus Life Sciences Limited	The firm presented the proposal for amendment in Phase IV clinical trial titled "A Phase IV prospective, multicentre, open-label, single arm study to evaluate the safety and efficacy of Trastuzumab Emtansine (UJVIRATM; Cadila Healthcare Ltd) in HER2- positive metastatic breast cancer patients". The committee noted that the firm has presented the protocol no. TDM1.21.001 version 4.0 instead of version 2.0 After detailed deliberation, the committee recommended for the approval of the presented protocol. The firm should submit the latest version of the protocol along with summary of changes in tabular format to CDSCO for further evaluation.
SND Division			
5.	SND/IMP/22/000075 Thiotepa Powder and Solvent for infusion 400 mg	M/s. Intas Pharma	The firm presented their proposal for grant of permission to import and market Thiotepa Powder and Solvent for infusion 400 mg Bag. After detailed deliberation, the committee recommended for approval of permission for import and marketing of Thiotepa Powder and Solvent for infusion 400 mg bag.

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6.	SND/IMP/22/000071 Acalabrutinib Tablets 100 mg	M/s. AstraZeneca Pharma India Limited	The firm presented their proposal for grant of permission to import and market of Acalabrutinib Tablets 100 mg. After detailed deliberation, the committee recommended for approval of permission for import and marketing of Acalabrutinib Tablets 100 mg.
GCT Division			
7.	CT/70/21 Online submission (20497) Polatuzumab Vedotin	M/s. Roche Products	The applicant has presented their proposal for increase of no. of subjects from 10 to 14 from India. After detailed deliberation, the committee approved the proposal for increase of no. of subjects from 10 to 14 from India.
8.	CT/109/22 Online submission (34031) SAR408701	M/s. Sanofi	The applicant has presented Phase III clinical trial protocol no EFC15858, amended protocol 04, version no. 1 dated 21-07-2021 before the committee. After detailed deliberation, the committee recommended for the conduct of the study as per protocol with condition that the firm/sponsor and site/investigator should report all SAEs including death irrespective of its causality (viz. PD) to the CDSCO as per the provisions of NDCTR, 2019 and the study protocol is to be added with country specific addendum.
9.	CT/25/16 Online submission (5331) Abemaciclib	M/s. Eli-Lilly	The firm did not turn up for presentation.
10.	CT/110/22 Online Submission (34090) Xevinapant	M/s. IQVIA	The firm presented the proposed Phase III study protocol no. MS202359_0002, Version 2.0 dated 28-Apr-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions- 1. The firm/Sponsor and site/Investigator should report all SAEs including death irrespective of its causality (viz. PD) to the CDSCO as per the provisions of NDCTR, 2019 and the study

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			protocol is to be added with country specific addendum. 2. The firm/Sponsor should increase proposed no of subjects from India in the study. NB: Dr. Atul Sharma did not participate in the deliberation.
11.	CT/84/22 Online Submission (33550) Decitabine 5mg + Tetrahydrouridine 250mg	M/s. Novo-Nordisk	The firm presented the proposed Phase II study protocol no. NN7533-4470, Version 6.0 dated 07-Aug-2022 (ASCENT-1) before the committee. After detailed deliberation, the committee recommended the conduct of the study as per the protocol.
12.	CT/117/22 Online Submission (34226) Fitusiran (SAR439774)	M/s. Sanofi Healthcare	The firm presented the proposed Phase III study protocol no. EFC17574, Version 1.0 dated 04JUL2022 (ATLAS-neo study) before the committee. After detailed deliberation, the committee recommended the conduct of the study with the following conditions: 1) Sponsor should provide the standard of care and rescue medication during the study free of cost to the study participant(s). The same should also be a part of the study informed consent document. 2) Sponsor should submit the detailed and comparative of the Phase I and Phase II study data with IP in subjects with Hemophilia A or B with inhibitor or non inhibitor to CDSCO.