Recommendations of the SEC (Oncology & Haematology) made in its 156th meeting held on 12.09.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2022/35249 Ipilimumab 5mg/ml concentrate for solution for Infusion	M/s. BMS	The firm didn`t turn up for presentation.
SND Division			
2.	SND/MA/23/000173 Ferric Carboxymaltose injection 50mg/ml	M/s. Emcure Pharmaceuticals Limited	The firm presented the proposal for manufacture and marketing of Ferric Carboxymaltose injection 50 mg/ml indicated for the treatment of iron deficiency in children and adolescents aged >1 year when oral iron preparations are ineffective or cannot be used (Additional Indication) along with justification/rational for clinical trial waiver before the committee. The firm has informed that Ferric Carboxymaltose injection 50 mg/ml is already approved in USFDA (2022) and by EMEA (2023) for the treatment of pediatrics patients with Iron Deficiency Anemia. After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Ferric Carboxymaltose injection 50 mg/ml for proposed additional indication with clinical trial waiver subject to condition that the firm should conduct Phase IV clinical trial in 300 pediatrics children and adolescents aged > 1 year age. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 03 months from the date of approval for further review by the committee.
GCT Division			
3.	CT/143/22 Online Submission (26154) (VAYHIT2)	M/s. Novartis	The firm presented proposal for waiver of condition no. I of clinical trial permission for protocol No. CVAY736Q12301 After detailed deliberation, the committee

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			recommended that the condition (i) of clinical trial NOC may be modified as "The applicant should submit interim safety data of 50 global subjects (including first 15 enrolled subjects from the country) for review by the committee, while the trial can be continued.
4.	CT/110/22 Online Submission (26486) Xevinapant	M/s. IQVIA	The firm presented protocol amendment V3.5 dated 06 March 2023 and updated ICF v3.0 dated 16-Nov-2022 for protocol No. MS202359_0002. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented.
5.	CT/54/23 Online Submission (37470) Naptumomab Estafenatox	M/s. PFC Pharma	The firm presented Phase Ib, clinical trial for protocol No. 127-Cl-01 (NT-NAP-101). After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
6.	CT/86/23 Online Submission (38577) TK-112690	M/s. Biosphere Clinical Research	The firm presented Phase IIa clinical trial for protocol No. CLP-2690-0008, 1.0 dated, 01-July-2023. After detailed deliberation, the committee recommended that the proposal should be re-deliberated in presence of the Radiation Oncologist and the firm should submit the following: 1. Adverse Event Reports of all previous studies. 2. Global Regulatory status of the drug.
7.	CT/136/21 Online Submission (25868) Belantamab Mafodotin (GSK2857916)	M/s. GSK	The firm presented protocol amendment 02 dated 19 December 2022 for protocol No. 209628. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm subject to condition that IDMC report shall be submitted.
8.	CT/25/23 Online Submission (36553) D8531C00002	M/s. Labcorp	In light of the earlier recommendation dated 08.06.2023, the firm presented the adverse event data of Phase II clinical trial and details of cardiac standard to be adopted during Phase III clinical trial before the committee.

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			After detailed deliberation, the committee recommended for grant of permission to conduct the study with the following conditions: 1. Heart rate shall be continuously monitored rather than once in two months. 2. SOP for proper management of bradycardia shall be mentioned in the study protocol. Accordingly, the firm should submit revised protocol to CDSCO.
9.	CT/39/23 Online Submission (37172) Serpin PC	M/s. InVentiv International Pharma	The firm presented Phase 2b clinical trial protocol No. AP-0103. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with condition that: 1. Details of study AP-0105 shall be excluded from the protocol. 2. Full time institutional PI shall be included in the study. Accordingly, revised protocol should be submitted to CDSCO.
10.	CT/74/18 Online Submission (24366) Durvalumab or Durvalumab & Tremelimumab	M/s. AstraZeneca	The proposal was deferred for next SEC meeting.
11.	CT/29/21 Online Submission (25364) Larotrectinib	M/s. Bayer Pharmaceuticals	The proposal was deferred for next SEC meeting.
12.	CT/46/22 Online Submission (26546) Datopotamab Deruxtecan (DATO-DXD, DS-1062	M/s. AstraZeneca	The proposal was deferred for next SEC meeting.
New Drug Division			

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13.	ND/MA/23/000111 Relugolix Tablets 120mg	M/s. BDR Pharmaceuticals Ltd.	The firm presented their proposal to conduct Bioequivalence study and justification for clinical trial waiver before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Bioequivalence study as per the presented protocol. The firm should submit Bioequivalence study report for further review by committee.
FDC Division			
14.	FDC/MA/22/000258 Ferrous Bis Glycinate IH 10mg+ Vitamin B12 IP 0.8mcg+ Vitamin D3 IP 20mcg + Folic acid IP 100mcg Lotion	M/s. Murli Krishna Pharma Pvt. Ltd.	In light of earlier SEC recommendation dated 11.05.2023 the firm presented the pre-clinical study results along with Phase III clinical trial protocol. After detailed deliberation, the committee considered the pre-clinical study results and recommended that firm should submit the PK study protocol as well as revise the Phase III clinical trial study protocol on following points : 1. Duration of study and dose should be mentioned. 2. Inclusion and exclusion criteria should also be as per NDCT Rules, 2019. In view of above, the protocols should be presented before SEC for review.