Recommendations of the SEC (Oncology &Haematology)made in its 160th meeting held on 30.10.2023 & 31.10.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
BiologicalDivision			
1.	BIO/CT04/FF/2023/38230 Bevacizumab 400 mg/16 ml Concentrate for solution for infusion	M/s. Lambda Therapeutics	The firm presented the study protocol titled "A Randomized, Double-Blind, Two-Arm, Single Intravenous Infusion Dose, Parallel, Trial Assessing, Bioequivalence and Safety of Biosimilar Bevacizumab of Aryogen Pharmed versus Avastin of Roche in Healthy, Adult, Human, Male Subjects" vide protocol no 0338-22 version 02 dated 06.06.2023. After detailed deliberation, the committee recommended to conduct the study as per the presented protocol with the condition to revise the study title as comparative pharmacokinetic study replacing bioequivalence study. Accordingly, firm should submit the revised protocolto CDSCO.
SND Division			
2.	SND/CT/23/000052 Desidustat Tablets 25mg, 50mg & 100mg	M/s. ZydusLifesciences Limited	The firm presented the study protocol entitled "A Phase-IIa, double blind, randomized, placebo controlled, parallel, multicenter, proof-ofconceptstudy to evaluate the efficacy and safety of Desidustat oral tablet for treatment of sickle cell disease." Protocol No.: DESI.23.001 Version 01, datedJuly 12, 2023 before the committee. After detailed deliberation, the committee recommended to conduct the Phase-IIa study as per protocol presented by the firm.
3.	SND/MA/23/000197 Apalutamide Tablets 60mg	M/s. Hetero Labs Limited	The firm presented the proposal for grant of manufacture and market of Apalutamide tablets 60mg along with BE study results before the committee. The firm informed that Apalutamide tablets 60mgis already approved by CDSCO dated 18.11.2022 for proposed indication. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Apalutamide

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			tablets 60mg for already approved indication subject to condition that firm should conduct Phase-IV clinical trial. In addition to above, the firm should fulfil the requirement of CMC data. Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months of approval of the drug for further review by the Committee.
GCT Division			
4.	CT/110/20 Online Submission (21777) Durvalumab	M/s. AstraZeneca	The firm presented protocol amendment version 4.0 dated 12.04.2022 protocol No. D910FC00001 After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
5.	CT/99/21 Online Submission (26372) DRB436, TMT212	M/s. Novartis	The firm presented protocol amendment version 03 dated 28.02.2023 protocol No. CDRB436J12301 After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
6.	CT/76/23 Online Submission (38014) Iberdomide	M/s Bristol-Myers Squibb	The firm presented Phase III clinical trial protocol No. IM048022. After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
7.	CT/42/22 Online Submission (27174) Olaparib	M/s. Labcorp	The firm presented protocol amendment version 6.0 dated 24.01.2023 protocol No. D9311C00001 After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
8.	CT/164/21 Online Submission (27254) Zanidatamab (ZW25) Tislelizumab (BGB-A317)	M/s. PPD	The firm didn't turn up for the presentation.
9.	CT/88/23 Online Submission	M/s. Parexel	The firm presented Phase IIIB clinical trial protocol No. D4191C00137.

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	(37853) Durvalumab (MEDI4736) Concentrate for solution for infusion 50 mg/mL (500 mg/vial)		After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
10.	CT/155/22 Online Submission (27593) Pembrolizumab 200mg + Vibostolimab 200mg	M/s. MSD Pharmaceuticals	The firm didn't turn up for the presentation.
11.	CT/95/23 Online Submission (38850) Pertuzumab (r-DNA origin) injection 420 mg/14 mL vial (Bmab 1500) or PERT-IJS	M/s. Biocon Biologics Limited	The firm presented Phase III clinical trial protocol No. BIO-PERTUZ-301. After detailed deliberation, the committee recommended for submission of following: 1. Clarification for statistical part of the protocol. 2. TDM1 has to be made mandatory and should be provided free of cost. 3. Details of pathological evaluations to be done. Accordingly, the firm should submit the above information for re-deliberation by the SEC.
12.	CT/123/21 Online Submission (27785) NeoadjuvantTrastuzumabDeruxtecan (T-DXd) Monotherapy or T-DXd	M/s. AstraZeneca	The firm presented protocol amendment version 8.0 dated 28.07.2023 protocol No. D967RC00001 After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm with condition that enrollment of number of Indian patients should be proportionately increased from 50 to 75
13.	CT/100/23 Online Submission (39063) Tislelizumab (also known as BGB-A317)	M/s. B10 Health Technologies Private Limited	The firm presented Phase II clinical trial protocol No. BGB-A317-001-PH After detailed deliberation, the committee recommended for grant of permission to conduct the trial with condition that data from this trial should not be used for marketing authorization.

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14.	CT/98/23 Online Submission (38914) Cemdisiran (ALN-CC5) 200 mg/ml Solution for subcutaneous administration + Pozelimab (REGN3918) 200 mg/ml Solution for intravenous or subcutaneous administration	M/s. Parexel	The firm presented Phase III clinical trial protocol No. R3918-PNH-2050. After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
15.	CT/141/22 Online Submission (26866) VAY736 (Ianalumab)	M/s. Novartis	The firm didn't turn up for the presentation.
New Drug Division			
16.	ND/CT21/FF/2022/35530 Ferumoxytol Injection 510mg Elemental Iron/17ml (30mg/ml)	M/s. MSN Laboratories Pvt. Ltd.	In light of the earlier SEC recommendation dated 11.04.2023, the firm presented preclinical studies-Repeated dose toxicity study data, BE study protocol and global clinical trial data involving Indian population carried out by the innovator along with the request of Phase III clinical trial waiver and grant of permission to conduct bioequivalence study before the committee. The committee reviewed the preclinical studies-Repeated dose toxicity data, BE study protocol and global clinical trial data involving Indian population carried out by the innovator. After detailed deliberation, the committee recommendedfor grant of permission to conduct the pharmacokinetic study as per thepresented protocol and submit the report for further evaluation by the committee.
17.	ND/CT/20/000068 Abemacicilib Tablets 50mg	M/s. Eli Lily and Company	In light of earlier SEC recommendation dated 15.09.2020, the firm presented the Phase IV clinical trial report before the committee. The firm was granted permission to

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			import and marketing of Abemaciclib 50mg, 100mg, 150mg and 200mg film coated tablets vide permission no, IMP-ND-133-2019 dated 18.11.2019 wherein the condition no. 10 mentioned as "The firm should conduct a Phase IV clinical trial on about 200 patients for which protocol should be submitted within 3 months of approval and results should be submitted for review within 2 years of approval of the Phase IV clinical trial." After detailed deliberation, the committee considered and agreed to the result of the Phase IV clinical trial report.
18.	ND/CT/23/000037 Tenalisib 400mg Tablet	M/s. Syngene International Ltd	In continuation to recommendations of SEC meeting dated 11.07.2023, the firm presented Phase II protocol of Tenalisib tablets 400 mg in patients with metastatic triple negative breast cancer (TNBC). After detailed deliberation the committee recommended for grant of permission to conduct the trial as per the protocol presented by the firm. Note: Dr. Atul Batra didn`t participate in the deliberation.