Recommendations of the SEC (Oncology & Hematology) made in its 163rd meeting held on 21.12.2023 & 22.12.2023 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.	In light with earlier SEC (Oncology & Haematology) recommendation the firm presented their proposal for conduct Bio-equivalence study and Phase III clinical trial waiver for grant of permission to manufacture and market Ferric Maltol capsules 30 mg along with 28 days repeated dose toxicity data in Rats and New Zealand White Rabbit. After detailed deliberation, the committee recommended for grant of permission to conduct bio-equivalence study as per protocol presented subject to condition that firm should submit the major organs histopathological slides of repeated dose toxicity study to CDSCO. The committee also recommended that firm should submit bio-equivalence study results before the committee for further consideration.
2.	ND/MA/22/000166 Relugolix Tablets 120 mg	M/s. Alkem Laboratories Ltd.	In light of earlier recommendation dated 10-01.2023, the firm presented the BE study report before the committee. After detailed deliberation, the committee opined that the firm should submit the following before committee for further consideration: 1. Justification/clarification regarding significant Inter subject variability in presented BE study data. 2. Published PK/PD data 3. Data on ratio of serum to CSF concentration 4. Minimum effective concentration in CSF required for pharmacological action of proposed drug.
SND Division			
3.	SND/CT/23/000065 Ondansetron ER Intramuscular	M/s. Shilpa Medicare Private Limited	The firm presented the proposal for grant of permission to conduct Phase-III clinical trial titled "A Phase-III, Randomized, Multicentre, Double Blind,

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	Injectable Suspension 100mg/1ml		Parallel Group, Prospective, Non-Inferiority Study to Evaluate the Efficacy and Safety of Ondansetron Extended-Release Injectable Suspension Intramuscular When Compared to Ondansetron IM Injection for the Prevention of Chemotherapy Induced Nausea and Vomiting (CINV) in Patients Receiving Moderately and Highly Emetogenic Chemotherapy" of drug Ondansetron Extended-release (ER) intramuscular Injectable suspension 100mg/1ml along with Phase-III protocol (Protocol No. NV-05-1543-2023 Version No. 1.0 dated 29th Aug 2023) before the committee. The firm informed that the Ondansetron extended-release (ER) intramuscular injectable suspension 100mg/1ml is not yet approved anywhere. The committee noted that the justification submitted by the firm was not found scientifically adequate. After detailed deliberation, the committee recommended that the firm should submit PK-PD data of 3 cohorts for 7 days, minimum effective concentration of the drug and QT interval data at Tmax to CDSCO for further review by the committee.
4.	SND/MA/23/000254 Iron (III) Hydroxide Polymaltose Syrup 50mg/5ml	M/s. Ajanta Pharma Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Iron (III) Hydroxide Polymaltose syrup 50mg/5ml along with justification for waiver of Phase-III clinical trial before the committee. The committee noted that the firm has not provided the therapeutic clinical justification / published literature to support the clinical trial waiver. After detailed deliberation, the committee did not recommend for waiver of Phase-III clinical trial as it is not meeting the requirement of New Drugs and Clinical Trials Rules, 2019.

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5.	SND/MA/21/000266 Iron (III) Hydroxide Polymaltose Syrup 125mg/5ml)	M/s. Ajanta Pharma Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Iron (III) Hydroxide Polymaltose syrup 125mg/5mlalong with justification for waiver of Phase-III clinical trial before the committee. The committee noted that the firm has not provided the therapeutic justification / published literature to support the clinical trial waiver. After detailed deliberation, the committee did not recommend for waiver of Phase-III clinical trial as it is not meeting the requirement of New Drugs and Clinical Trials Rules, 2019.
6.	SND/MA/23/000267 Hydroxycarbamide Oral Solution 100mg /ml	M/s. Beta Drugs Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Hydroxycarbamide oral solution 100mg/ml along with justification for waiver of Phase-III clinical trial and bioequivalence study before the committee. After detailed deliberation, the committee recommended that the firm should submit pharmacokinetics data of Hydroxycarbamide oral solution 100mg/ml to CDSCO for further review by the committee.
GCT Division			
7.	CT/136/23 Online Submission (40261) 1. Datopotamabderuxtecan (Dato-DXd) 100mg/vial 2. Durvalumab (MEDI4736) 500mg/vial (50mg/Ml)	M/s. AstraZeneca	The firm presented Phase III clinical trial protocol No. D926QC00001. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm. Dr. Kausal Kalra PI didn't participate in this deliberation.
8.	CT/130/23 Online Submission (40068) Volrustomig	M/s. AstraZeneca	The firm presented Phase III clinical trial protocol No. D798AC00001. After detailed deliberation, the committee recommended for grant of permission to

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	(MEDI5752) Lyophilized Powder for solution for infusion 250 mg/vial (50 mg/Ml)		conduct the clinical trial as presented by the firm. Dr. Kausal Kalra PI didn't participate in this deliberation.
9.	CT/127/23 Online Submission (39951) Camizestrant film-coated tablets	M/s. Fortrea Development India Private Limited	The firm presented Phase III clinical trial protocol No. D8535C00001. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm. Dr. Kausal Kalra PI didn't participate in this deliberation.
10.	CT/123/23 Online Submission (39754) IMP-Giredestrant(RO7197597), Comparators-Fulvestrant, Palbociclib, Ribociclib, Abemaciclib	M/s. Roche Products (India)	The firm presented Phase III clinical trial protocol No. CO44657. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.
11.	CT/145/23 Online Submission (40513) Volrustomig (MEDI5752) Lyophilized product for concentrate for solution for infusion 250 mg (50mg/Ml)	M/s. AstraZeneca	The firm presented Phase III clinical trial protocol No. D798EC00001. After detailed deliberation, the committee opined that the firm should present data on efficacy of immunotherapy in PD-L1 negative and low (< 1% and upto 10%) patients for further review by the committee.
12.	CT/140/23 Online Submission (40457) Nivolumab (DRL_NU)	M/s. Dr. Reddy's Laboratories Limited	The firm presented Phase I/III clinical trial protocol No. NU-01-001. After detailed deliberation, the committee opined that the firm should present following for further review by the committee: 1. Recalculation of sample size considering 95% CI. 2. Efficacy of immunotherapy in PD-L1 negative and low (< 1% and upto 10%) patients. 3. Inclusion/exclusion criteria, Efficacy and safety endpoints should be same as innovator's

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			study design. 4. Detailed Kinetics study data should be submitted. 5. More geographically distributed Govt. sites should be included in the study.
13.	CT/138/23 Online Submission (39907) Luspatercept (BMS-986346/ACE-536)	M/s. Bristol-Myers	The firm presented Phase III clinical trial protocol No. CA056-025. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.
14.	CT/137/23 Online Submission (40392) 1.Datopotamab deruxtecan (Dato-DXd, DS-1062a) 100mg/vial2.Durvalumab (MEDI4736) 500mg/vial (50mg/mL)	M/s. AstraZeneca	The firm presented Phase III clinical trial protocol No. D7630C00001. After detailed deliberation, the committee opined that the firm should submit supportive documents for selection of Durvalumab dose 1120mg every three weeks instead of 1500mg and include more geographically distributed Govt. sites for further review by the committee.
15.	CT/81/18 Online Submission (28922) Durvalumab	M/s. AstraZeneca	The firm presented protocol amendment version 6.0 dated 28 August 2023 protocol No. D933YC00001. After detailed deliberation, the committee opined that more Justification/explanation is required to be submitted for further review by committee.
16.	CT/100/19 Online Submission (29458) LY3527723 (LOXO-292)	M/s. Eli Lilly	The firm didn't turn up for presentation
17.	CT/92/22 Online Submission (29561) Teclistamab	M/s. Johnson & Johnson	The firm presented protocol amendment 3 dated 14 June 2023 protocol No. 64007957MMY3005. After detailed deliberation, the committee opined that outcome of safety and efficacy of weight based doses in TRIMM-2 study concluded abroad should be submitted for further review by committee.
18.	CT/83/22 Online Submission (29176)	M/s. IR Innovate Research Private Limited	The firm presented protocol amendment 3 version 4.0 dated 06 June 2023 protocol No. BCD-201-2.

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	BCD-201		After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
19.	CT/55/21 Online Submission (29278) JNJ-17000139 Gemcitabine 225 mg intravesical delivery system (TAR-200)	M/s. Pharmaceutical Research Associates India	The firm presented protocol amendment 4 dated 05 October 2023 protocol No. 17000139BLC3001. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
20.	CT/64/19 Online Submission (28901) Concizumab	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented protocol amendment version 6.0 dated 22 June 2023 protocol No. NN7415-4307. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
21.	CT/110/22 Online Submission (29338) Xevinapant	M/s. IQVIA RDS	The firm presented protocol amendment version 5.0 dated 25 July 2023 protocol No. MS202359-0002. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
22.	CT/97/21 Online Submission (28916) Amivantamab and Lazertinib	M/s. Johnson & Johnson	The firm presented protocol amendment 6.0 dated 22 December 2022 protocol No. 61186372NSC3002. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
23.	CT/76/20 Online Submission (28914) Amivantamab	M/s. Johnson & Johnson	The firm presented protocol amendment 3 dated 07 August 2023 protocol No. 61186372NSC3001. After detailed deliberation, the committee recommended for approval of the OLE phase only. The committee did not recommend for LTE phase of the study.