Recommendations of the SEC (Oncology & Haematology) made in its 150th meeting held on 08.06.2023 at CDSCO HQ New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-07/08-DC Olaparib 100mg/150mg Film-Coated tablets	M/s. AstraZeneca	The firm presented the Phase IV clinical study report title, "A prospective, multicentre, Phase-IV clinical trial of Olaparib in Indian patients with platinum sensitive relapsed ovarian cancer who are in complete or partial response following platinum based chemotherapy and metastatic breast cancer with Germline BRCA1/2 mutation (SOLI Study D0816R00025)" before the committee. After detailed deliberation, the committee noted the results of the Phase IV clinical trial.
2.	ND/MA/23/000082 Nelarabine Injection 250mg/50ml (2.5mg/5ml)	M/s. MSN Laboratories	The firm presented the proposal for manufacture & marketing of Nelarabine Injection 250mg/50mL (5 mg/mL) along with request for BE waiver & local Phase III clinical trial waiver. The drug is indicated for the treatment of patients with T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens. This use is based on the induction of complete responses. Randomized trials demonstrating increased survival or other clinical benefit have not been conducted. The committee noted that the drug is approved in USA, EU as Orphan Drug. After detailed deliberation, the committee recommended for grant of permission for manufacturing & marketing of Nelarabine Injection 250mg/50mL (5 mg/mL) with BE waiver & local Phase III clinical trial waiver subject to following conditions: 1. The drug should be sold by retail under prescription of oncologist

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			only. 2. The firm should conduct Phase-IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO for further review by the committee.
3.	ND/IMP/21/000009 Darolitamide 300mg tablet	M/s. Bayer Pharma	The firm presented the proposal for update prescribing information for Darolutamide 300 mg film coated tablets (Nubeqa), changes version 4 to 5 (version No NU_2023_02 dated 24 Feb 2023 based on the updated company core data sheet (CCDS). After detailed deliberation, the committee recommended for grant of approval for the proposed update in prescribing information as presented by the firm.
Biological Division			
4.	BIO/CT18/FF/2022/ 35249 Ipilimumab 5 mg/mL concentrate for solution for infusion 50mg	M/s. Bristol-Myers Squibb India Pvt. Ltd	The firm presented the proposal for approval of additional indication i.e. Ipilimumab, in combination with Nivolumab, for the first-line treatment of adult patients with unresectable advanced or metastatic esophageal squamous cell carcinoma (ESCC) with request for local clinical trial waiver. After detailed deliberation, the committee recommended that the firm should submit the status of on-going Phase IV clinical trial of Nivolumab in combination with Ipilimumab and its interim report to CDSCO for further review by the committee.
5.	BIO/CT18/FF/2022/ 35291 Nivolumab 10 mg/mL concentrate for solution for infusion 40 mg & 100 mg	M/s. Bristol-Myers Squibb India Pvt. Ltd	The firm presented the proposal for approval of below additional indications with request for local clinical trial waiver: • <u>Urothelial Carcinoma (UC)</u> Nivolumab is indicated for the adjuvant treatment of adult patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection of UC • <u>Esophageal Squamous Cell Carcinoma (ESCC)</u> Nivolumab, in combination with fluoropyrimidine- and platinum-containing chemotherapy, is indicated for the first-line treatment of adult patients with unresectable advanced or metastatic

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			esophageal squamous cell carcinoma (ESCC) Nivolumab, in combination with ipilimumab, 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 recommended that the firm should submit the status of on-going Phase IV clinical trial of Nivolumab in combination with Ipilimumab and its interim report to CDSCO for further review by the committee.
6.	BIO/CT18/FF/2022/ 34156 Nivolumab 10 mg/ml concentrate for solution for infusion (40 mg & 100 mg)	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm did not turn up for presentation.
7.	BIO/CT18/FF2022/ 34766 Polatuzumab Vedotin for Injection, 30mg/vial and140 mg/vial	M/s. Roche Products(I) Pvt. Ltd	The proposal was deferred for next SEC meetings.
8.	BIO/CT18/FF/2022/ 34250 Teclistamab Sterile Liquid in Vials, 30 mg/vial (10 mg/ml) and 153 mg/vial (90 mg/ml)	M/s. Johnson & Johnson Pvt. Ltd.	The firm did not turn up for presentation.
9.	BIO/CT21/FF/2023/ 36429 Nimutuzumab Injection 50 mg/10 mL	M/s. Biocon Biologics Limited	The proposal was deferred for next SEC meetings.
SND Division			

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
10.	SND/MA/23/000054 Ferric carboxymaltose Injection 50mg/ml	M/s. Dr. Reddy's Laboratories Limited	In light of the earlier, SEC recommendations dated 27.04.2023, the firm submitted animal sub-acute toxicity data. After detailed deliberation, the committee recommended for grant of permission for manufacture and market of Ferric Carboxymaltose Injection 50 mg/ml in fill volumes 100mg/2ml, 500mg/10ml, 750 mg/15ml and 1000mg/20ml vials (Ferric Carboxymaltose Injection 50 mg/ml in 2 ml vial, 10ml vial, 15ml vial and 20 ml vial) for additional pack sizes.
11.	SND/IMP/23/000043 Darolutamide Tablets 300mg	M/s Bayer Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for grant of permission to import and marketing of already approved drug product Darolutamide 300 mg film coated tablets with additional indication "darolutamide is indicated for the treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with Docetaxel." The committee agreed to clinical trial waiver on the basis of therapeutic rationale and justification for clinical trial waiver submitted by the firm. After detailed deliberation, the committee recommended for the grant of permission for import and market of already approved drug product Darolutamide 300 mg film coated tablet for additional indication "Darolutamide is indicated for the treatment of patients with metastatic hormone sensitive prostate cancer (mHSPC) in combination with docetaxel".
GCT Division			
12.	CT/25/23 Online Submission (36553) Camizestrant	M/s. Labcorp	The firm presented the Protocol no. D8531C00002 version 2.0 dated 14Dec 2022 for grant of permission for conduct of Phase III Clinical Trial. After detailed deliberation, the committee recommended that the firm should submit details as follows: – (i) The Adverse Event data of Phase II clinical trial (ii) Cardiac standard to be adopted during the phase III

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			clinical trial. Accordingly, the firm should submit the above details to CDSCO for further review by the committee.
13.	CT/147/22 Online Submission (34864) VAY736 (Ianalumab)	M/s. Novartis	The firm has presented phase III clinical trial protocol no CVAY736I12301; Version number: 02, dated 22 Sep 2022 before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the clinical trial subject to the following conditions- 1. Protocol section 6.8.3 w.r.t Rescue therapy should be modified as per current guidelines for treatment of ITP. 2. Background therapy/Rescue medication i.e. platelet transfusion, corticosteroids and IVIG, etc, should be provided free of cost to the trial subjects throughout the conduct of the study.
14.	CT/105/22 Online Submission (33987) Phesgo (Pertuzumab + Trastuzumab)	M/s. Roche	In light of the earlier SEC recommendations dated 28.03.2023 & 29.03.2023, the firm presented phase III clinical trial protocol no WO43571, version 2 dated 19-05-2022, along with the summary of changes from previous protocol version, before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct the proposed study.
15.	CT/38/23 Online Submission (37151) Serpin PC	M/s. Inventive International Pharma Services	The proposal was deferred for next SEC meetings.
16.	CT/70/21 Online Submission (23341) Polatuzumab Vedotin	M/s. Roche	The firm presented the proposal along with protocol amendment no. 8.0 dated 19--October 2022 in Global Clinical Trial protocol no. MO40598 for approval before the committee. After detail deliberation, the committee recommended for grant of approval for the protocol amendment as presented by the firm.
17.	CT/57/21 Online Submission (24196)	M/s. Pfizer	The firm presented the proposal along with protocol amendment no. 5 dated 20-Dec-2022 in Global Clinical Trial protocol no. C4221015 for approval

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Encorafenib		before the committee. After detail deliberation, the committee recommended for Protocol amendment no. 5 dated 20 Dec 2022 in Global Clinical Trial Protocol no. C4221015 as presented by the firm.
18.	CT/35/23 Online Submission (36619) CC-92480 (BMS-986348) Mezigdomide	M/s. Bristol-Myers	The proposal was deferred for next SEC meetings.
19.	CT/131/22 Online Submission (25294) Marstacimab Prophylaxis	M/s. Pfizer	The proposal was deferred for next SEC meetings.
20.	CT/15/20 Online Submission (22812) Azacitidine with or without MBG453	M/s. Novartis	The proposal was deferred for next SEC meetings.
21.	CT/33/23 Online Submission (36892) Pacritinib	M/s. PSI CRO	The proposal was deferred for next SEC meetings.
22.	CT/83/22 Online Submission (25324) BCD-201-2	M/s. IR Innovate Research	The proposal was deferred for next SEC meetings.
23.	CT/75/21 Online Submission (23014) PF-06741086 (Marstacimab)	M/s. Pfizer	The proposal was deferred for next SEC meetings.
24.	CT/17/22 Online Submission (25272) Durvalumab (MEDI4736) Domvanalimab (AB154)	M/s. AstraZeneca	The proposal was deferred for next SEC meetings.
25.	CT/166/21 Online Submission (25957)	M/s. Labcorp	The proposal was deferred for next SEC meetings.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Acalabrutinib		