Recommendations of the SEC (Oncology) made in its 01/24 meeting held on 09.01.2024 & 10.01.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/155/23 Online submission (40636) Dated 01/12/23 ISB 1442	M/s Glenmark Pharmaceuticals Ltd.	The firm presented Phase I/IIa clinical study protocol No.ISB-1442-101. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/105/22 Online Submission (28558) Dated 18/09/2023 Giredestrant	M/s. Roche	The firm presented protocol amendment version 3 dated 18 November 2022 and protocol amendment version 4 dated 28 June 2023, protocol No. WO43571. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
3.	CT/36/22 Online Submission (28991) Dated 10.10.2023 Selpercatinib	M/s Eli Lilly	The firm presented protocol amendment (g) dated 28 April 2023 and (h) dated 17 August 2023, protocol No. J2G-MC-JZJX. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm.
4.	CT/100/19 Online Submission (29458) Dated 29/08/2023 LY3527723 (LOXO-292)	M/s. Eli Lilly	The firm presented protocol amendment (i) dated 11 August 2023, protocol No. J2G-MC-JZJB. After detailed deliberation, the committee recommended for approval of the protocol amendment as presented by the firm
5.	CT/37/22 Online Submission (30171) Dated 14/12/23 Hafnium Oxide PO4 Water for injection	M/s. PRA	The firm presented to waive off protocol amendment NOC condition No. (2) i.e oral cavity tumors should be excluded from the study vide protocol amendment 2.0 version No. 3.0 dated 29-JUL-2022 No.:NANORAY-312) After detailed deliberation, the committee recommended to waive off the protocol amendment NOC condition No.(2)
6.	CT/81/18 Online Submission	M/s. AstraZeneca	The firm did not turn up for presentation.

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	(28922) Dated 10/10/2023 Durvalumab		
Biological Division			
7.	BIO/CT18/FF/2023/39436 Nivolumab 10 mg/mL concentrate for solution for infusion	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented their proposal for approval of additional indication for the drug product Nivolumab 10mg/mL concentrate for solution for infusion based on the clinical data generated from global clinical trial with request for local clinical trial waiver. The committee noted that drug is already approved and sufficient safety data is established. After detailed deliberation, the committee recommended for approval of the proposed additional indication with local clinical trial waiver.
8.	BIO/CT/23/000124 Bevacizumab 100mg/4mL concentrate for solution for infusion	M/s Enzene Biosciences Ltd	The firm presented the proposal to conduct Phase IV clinical trial titled "A prospective, multicenter, Open labelled, Phase IV study to Establish the Safety & efficacy of Biosimilar Bevacizumab of Enzene Biosciences Ltd. in Combination with Chemotherapy in Patients with Metastatic Colorectal Cancer"vide Protocol No: ALK33/ENZ137-BEV2 Version 1.0 dated 28.08.2023. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per the protocol presented by the firm
9.	BIO/CT21/BO/2023/38170 Cetuximab 100 mg/20 ml	M/s Enzene Bio sciences	The firm presented their proposal for approval of additional indications by the way of extrapolation for the drug product Cetuximab 100 mg/20mL (r-DNA origin) Solution for Intravenous Infusion in vial. After detailed deliberation, the committee noted that there is an ongoing Phase IV study with the Enzene Cetuximab 100 mg/20mL (r-DNA origin) Solution for Intravenous Infusion in vial and accordingly the committee recommended that the firm should present the Phase IV clinical data upon completion of the

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			study for review by the committee for further consideration of proposed additional indications.
10.	BIO/CT21/BO/2023/38200 Bevacizumab 100 mg/4mL and Bevacizumab 400 mg/16mL	M/s Enzene Bio sciences	In light of earlier SEC recommendation dated 09.11.2023 and 10.11.2023, the firm presented the proposal for approval of additional indications in line with the indications approved for the innovator product with local clinical trial waiver by the way of extrapolation of indications. After detailed deliberation, the committee recommended for approval of the proposed additional indications in line with indications approved for the innovator product with local clinical trial waiver by way of extrapolation of indications except for the indication i.e. "for unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer with Epidermal Growth Factor Receptor (EGFR) activating mutations" for which there is no data in Indian population.
11.	BIO/CT21/BO/2023/38835 Trastuzumab 150mg and 420mg	M/s Curateq	In light of earlier SEC recommendations dated 09.11.2023 and 10.11.2023, the firm presented the immunogenicity data of patients in Phase III clinical trial conducted by the firm in India for seeking approval to manufacture and market Trastuzumab 150mg and 420mg lyophilized powder for concentrate for solution for infusion in single dose vial. After detailed deliberation, the committee recommended for grant of marketing authorization to the firm for Trastuzumab 150mg and 420mg lyophilized powder for concentrate for solution for infusion in single dose vial subject to the condition that the firm should conduct Phase IV clinical trial in the country. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of marketing approval.
12.	BIO/CT04/FF/2023/40510	M/s Curateq	The firm presented the proposal to conduct Phase III clinical trial titled "A

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	Bevacizumab 25 mg/mL concentrate for solution for infusion		Prospective, Randomized, Double Blind, Multicentric, Parallel Group Phase-III Clinical Study to Evaluate the Efficacy, Safety and Immunogenicityof BP01 (Bevacizumab) Versus EU approved Avastin® along with chemotherapy XELOX in metastatic colorectal cancer patients"vide Protocol No. ICS/CUR/2023-006 Version 1.0 dated 19.10.2023. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical study as per the protocol presented by the firm.
13.	BIO/CT04/FF/2022/31422 Brentuximab Vedotin 50 milligram (mg)	M/s Takeda	In light of earlier SEC recommendations dated 23.06.2022, the firm presented the revised protocol Version 4.0 dated 8 Aug 2023 for conduct of Phase IV study of BrentuximabVedotin 50 milligram (mg) vial. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per the revised protocol Version 4.0 dated 8 Aug 2023presented by the firm.
14.	4-25/Roche/PAC-R-Atezolizumab-2022-BD(Diary no 6987) Atezolizumab injection 1200mg/20ml and 840mg/40mg vial	M/s Roche	The firm did not turn up for presentation
15.	BIO/CT18/FF/2023/39717 Atezolizumab Injection (1875mg/15ml vial)	M/s Roche Products (India) Pvt. Ltd.,	The firm presented their proposal for grant of permission to import and market Atezolizumab Injection (1875mg/15ml vial) (Tecentriq) by new route of administration i.e., Subcutaneous route for indications of Atezolizumab injection approved for Intravenous (IV) route for sale or for distribution in India with local Phase III and Phase IV clinical trial waiver for under unmet need in India. The committee noted that the i.v formulation of Atezolizumab is already available in market. Further, the

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			committee noted that the formulation and dose of proposed s.c route is different from i.v route and also India was not part of the global clinical study conducted to establish safety and efficacy data for new route of administration i.e. s.c route. After detailed deliberation, the committee did not consider the firm's request for approval of Atezolizumab Injection (1875mg/15ml vial) (Tecentriq) by proposed s.c route of administration with waiver of local clinical trial. The committee recommended that the firm should conduct Phase III study to establish safety and efficacy of the product for the proposed s.c route.
16.	BIO/CT04/FF/2023/37705 Denosumab	Biocon	In light of earlier SEC recommendations dated 09.11.2023 and 10.11.2023, the firm presented the amended protocol titled "A Randomized, Double-blind, Two-arm, Single-dose, Parallel Group Study to Compare the Pharmacokinetics, Pharmacodynamics, Safety, and Tolerability of Bmab 1000 and EU-approved Xgeva® in Normal Healthy Male Volunteers" vide Protocol No. BIO-BM1000-103 Version: 2.0 dated 08.12.2023. After detailed deliberation, the committee recommended to conduct the proposed Phase-I PK/PD study as per the amended protocol presented by the firm.
17.	79/Johnson/Phase IV/17-BD Daratumumab	J&J	The firm did not turn up for presentation
BA/BE Division			
18.	File No. 12-09/2023/BA-BE/MISC-44/DC (BABE/CT05/FF/2023/39796) Leuprolide acetate for	M/s. Sun Pharmaceuticals Industries Limited	The firm presented Bioequivalence study protocol No. C1B03530, version No. 01 dated 18-Sep-2023. After detailed deliberation, the committee recommended for approval for conduct of the BE Study as presented by the firm.

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	depot suspension, 7.5mg/vial (1 Month Depot)		
SND Division			
19.	SND/CT/23/000078 Lipid Based Cabazitaxel Tablet 50mg	M/s Intas pharmaceuticals ltd	In light of earlier SEC recommendations dated 13.04.2021 & 15.04.2021, the firm presented Phase-I clinical trial report of Lipid Based Cabazitaxel Tablet 50mg along with Phase-II clinical trial protocol (Protocol No. 0128-23 Version No.1.1 Dated: 16.09.2023) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-II clinical trial of Lipid Based Cabazitaxel tablet 50mg as per protocol presented by the firm, subject to condition that the firm should include adequate number of Government hospital trial sites.
New Drug Division			
20.	12-01/23-DC(Pt-90) 5-Fluorouracil	AIIMS, Raipur	In light with earlier SEC recommendation dated 25.07.2023, the Study investigator AIIMS, Raipur presented revised protocol for the conduct of academic clinical trial with drug 5-Flurouracil. After detailed deliberation, the committee recommended for the grant of permission to conduct the academic clinical trial as per the protocol presented.
21.	ND/MA/23/000131 Avatrombopag Tablets 20mg	M/s BDR Pharmaceuticals International	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Avatrombopag tablet 20mg mg along with protocol for BE study and justification for the waiver of Phase III clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Bioequivalence study as per the protocol presented. The firm should submit Bioequivalence study report for

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			further review by committee.