Recommendations of the SEC (Oncology) made in its 12th/24 meeting held on 05.06.2024 & 06.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/112/23 Online Submission (32469) Inavolisib in combination with Phesgo®	M/s. Roche	The firm presented protocol amendment version 2.0 dated 30.01.2024 protocol no. WO44263. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/17/21 Online Submission (32360) Ruxolitinib and Panobinostat	M/s. Novartis	The firm presented protocol amendment version 05 dated 12.01.2024 protocol no. CINC424A2X01B. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
3.	BIO/CT21/FF/2024/43306 Pertuzumab 30mg/mL concentrate for solution for infusion	M/s. Zydus Life Sciences	The firm presented the proposal for approval of additional indication of Early breast cancer for the approved similar biologic Pertuzumab 30mg/mL concentrate solution for infusion (r-DNA origin) by the way of extrapolation with waiver of local clinical trial. After detailed deliberation, the committee recommended for approval of additional indication by the way of extrapolation with local clinical trial waiver with a condition to conduct Phase IV study in the proposed indication. Accordingly, the protocol to conduct the Phase IV study shall be submitted to CDSCO within three months of grant of permission for the proposed additional indication.
4.	BMS/DGHS/LUSP/004/2024 Luspatercept powder for solution for injection 25 mg and 75mg	M/s. BMS	The firm presented the proposal for approval of changes in the approved protocol no. CA056-023, Version 1 dated 02.09.2022 to revised protocol Version 2 dated 18.10.2023 for the conduct of Phase IV study of drug product Luspatercept powder for solution for injection 25mg and 75 mg lyophilized powder for solution for injection in a vial (r-DNA origin).

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			After detailed deliberation, the committee recommended for approval of protocol version 02 dated 18.10.2023 (Major amendment) for the conduct of Phase IV study of Protocol No. CA056-023.
5.	r-DNA-11011(18)/74/2024-eoffice Tremelimumab concentrate for solution for infusion 20 mg/mL	M/s. Astra Zeneca	The firm presented the proposal for expansion of warning statement for approved drug Tremelimumab Concentrate for Solution for infusion 20 mg/ml (25 mg/1.25 ml and 300 mg/15 ml presentations) in single dose vials from "To be sold by retail on the prescription of a registered oncologist only" to "To be sold by retail on the prescription of a registered oncologist/ gastroenterologist only". The committee noted that the drug is not yet launched in Indian market. After detailed deliberation, the committee recommended that the proposal for expansion of warning statement may be considered after submission of first year PSUR data and subsequent review of the same by the committee.
6.	BIO/CT18/FF/2023/40657 Elranatamab Solution for Injection	M/s. Pfizer Products India Private Limited	In light of earlier SEC recommendation dated 03.04.2024, the proposal was redeliberated for grant of permission to import and market Elranatamab solution for injection 44mg/1.1mL (40mg/mL) and 76 mg/1.9mL (40mg/mL) along with request for local clinical trial waiver. The committee noted that no new data/literature/updates has been presented by the firm. After detailed deliberation, the committee reiterated the earlier SEC recommendation dated 03.04.2024. "The firm presented the proposal for grant of permission to import and market of Elranatamab solution for injection 44 mg/1.1 mL (40 mg/mL) and 76 mg/1.9 mL(40 mg/mL) along with request for local clinical trial waiver. The drug is indicated as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who

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			have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. The committee noted that the drug has an accelerated approval (conditional approval) in USFDA for proposed indication based on Phase II clinical trial data and the trial is ongoing. After detailed deliberation, the committee did not consider the firm's request for waiver of local clinical trial for grant of permission to import and market Elranatamab solution for injection."
BA/BE Division			
7.	File No. 12-09/2023/BA-BE/MISC-36/DC (BABE/CT05/FF/2024/42203) Zanubrutinib Tablets 320mg	M/s. Cliantha Research Ltd.	The firm presented the protocol no. C1B04034 Version 1 Dt 16-1-2024 & C1B04035 Version 1 Dt 16-1-2024 for conducting BA/BE study for export purpose only. After detailed deliberation, the committee recommended for the grant of permission to carry out BA/BE study for export purpose only .
SND Division			
8.	SND/MA/24/000052 Abiraterone Tablets 1000mg (Additional strength)	M/s. MSN Labs Private Limited	The firm did not turn up for presentation
9.	SND/MA/23/000234 Ondansetron ER Injectable Suspension 100mg/1ml	M/s. FTF Pharma Private Limited	In light of earlier SEC recommendation dated 03.04.2024 & 04.04.2024. Now, the firm presented revised Phase-III clinical trial protocol (Protocol No. 004/ACRS/CINV/FTF/2023 Version No. 2.0 Dated: 29.04.2024) before the committee. After detailed deliberation, the committee recommended to conduct Phase-III clinical trial as per revised protocol presented by the firm.

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New Drugs Division			
10.	ND/MA/23/000165 Nelarabine 250mg/50ml Injection	M/s. Zydus LifeScience Ltd.	The firm presented their proposal for manufacture & marketing of Nelarabine Injection 250mg/50mL (5 mg/mL) along with a 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 (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens. The committee noted that the drug is approved in USA, EU as an 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 the following conditions: 1. The drug should be sold by retail under prescription of Oncologist only. 2. The firm should conduct Phase-IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within three months of approval for further review by the committee.
11.	ND/CT/24/000026 Relugloix Tablets 120 mg	M/s. Sun Pharmaceutical Industries Ltd.	The firm presented their Phase-IV clinical trial protocol to assess the safety and efficacy of Relugolix Tablets 120 mg indicated for the treatment of advanced prostate cancer as per the condition of manufacture & marketing permission granted by this office. After detailed deliberation the committee recommended for conduct of trial as presented by the firm.

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12.	ND/CT/22/000096 Fosnetupitant 235mg and Palonosetron 0.25mg (Concentrate solution for infusion)	M/s. Glenmark Pharmaceuticals Ltd.	Firm presented Phase IV clinical trial of new drug Fosnetupitant 235mg and Palonosetron 0.25mg (Concentrate solution for infusion). After detailed deliberation, the committee noted the phase IV clinical trial report and found same in accordance with the approved phase IV clinical trial protocol.