Recommendations of the SEC (Oncology) made in its 15th/24 meeting held on 23.07.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/97/22 Online Submission (28966) Pertuzumab-Trastuzumab Injection 600mg + 600mg/10ml vial(PH FDC SC / Phesgo®) Pertuzumab-Trastuzumab Injection 1200mg+ 600mg/15ml vial(PH FDC SC / Phesgo®) Pertuzumab Injection 420mg/14ml (Perjeta®)Trastuzumab for Injection 150mg (Herceptin®/ Herclon®)Trastuzumab Emtansine for Injection 160mg (Kadcyla®)	M/s. Roche Products (India) Private Limited	In light of earlier SEC recommendation dated 16.04.2024, the firm presented protocol amendment version 2.0 dated 15.11.2022 protocol No. MO43110 and protocol amended for arrangement of institutional based administration of drugs. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with condition that drug shall be administered under supervision of Medical Oncologist.
2.	CT/153/23 Online Submission (40374) Repotrectinib (BMS-986472, TPX-0005)	M/s. Bristol-Myers Squibb India	In light of earlier SEC recommendation dated 23.01.2024 and 24.01.2024, the firm presented Phase III clinical study protocol No. CA127-1030 version 01 dated 12 May 2023 After detailed deliberation, the committee recommended for grant of permission to conduct the trial with sample size of 20 patients as presented by the firm.
3.	CT/111/23 Online Submission (32604) Daratumumab	M/s. Spectrum Clinicat Research	The firm presented protocol amendment version 02 dated 05.02.2024 protocol No. BCD-264-2/DARVIVA. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/140/23 Online Submission (33251) Nivolumab 40 mg/4 ml,	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented protocol amendment version 3.0 dated 23.04.2024 protocol No. NU-01-001.

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	Nivolumab 100 mg/ 10 ml		After detailed deliberation, the committee recommended for approval of protocol amendment with the condition that investigator shall be Medical Oncologist at each site.
Biological Division			
5.	4-25/Roche/PAC-R-Atezolizumab-2022-BD (Diary no E-32557) Atezolizumab injection 1200mg/20ml and 840mg/14mLvial	M/s. Roche	The firm did not turn up for the presentation.
6.	E-40798 Atezolizumab Injection (1875mg/15ml vial)	M/s. Roche	In light of the earlier SEC recommendations dated 09.01.2024, 19.03.2024, 20.03.2024 and 15.05.2024, the proposal of the firm was redeliberated for grant of permission to import and market Atezolizumab injection (1875mg/15ml vial) (Tecentriq) by new route of administration i.e., subcutaneous route for 03 monotherapy indications approved for intravenous (IV) route for sale or for distribution in India with local Phase III clinical trial waiver along with the commitment to conduct Phase IV study. The committee noted the results of Atezolizumab by subcutaneous (SC) route Global Clinical Studies: IMSCIN001/IMSCIN002 where in India was not the part of the study. The committee also noted that there is a change in route of administration of proposed product and data needs to be generated in Indian Population. After detailed deliberation, the committee reiterated the earlier SEC recommendations dated on 09.01.2024, 19.03.2024, 20.03.2024 and 15.05.2024.
7.	BIO/CT21/BO/2024/ 42622 Denosumab 120mg/1.7mL solution for injection	M/s. Hetero Biopharma Limited	The firm presented the proposal for grant of permission to manufacture and market Denosumab 120mg/1.7ml solution based on the results of comparative Phase III clinical trial conducted in India to establish the efficacy, safety, pharmacokinetics and immunogenicity of the drug product for

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			the indication of prevention of skeletal related events in adults with advances malignancies involving bone. After detailed deliberation, the committee recommended for grant of approval to manufacture and market Denosumab 120mg/1.7ml solution for the indication i.e. Prevention of skeletal related events in adults with advances malignancies involving bone subject to the condition that firm shall conduct Phase IV study in the country. Accordingly, the protocol to conduct the Phase IV study shall be submitted within three months of grant of marketing authorization permission to manufacture and market the product. Dr. Kaushal Kalra and Dr. Sameer Bakshi did not participate in this proposal.
8.	E-33477, E-18726 Teclistamab solution for injection 10mg and 90mg	M/s. Johnson & Johnson Pvt. Ltd.	The firm presented the proposal for the revision in prescribing information based on EU SmPC dated 22. 06. 2023, 20.07.2023 and 07.12.2023 for Teclistamab Solution for Injection 30 mg/vial (10mg/ml) & 153 mg/vial (90mg/ml) with respect to changes in dosage and administration, pregnancy, breast feeding & fertility, pharmacokinetic properties, special warning and precautions for use, undesirable effects etc. After detailed deliberation, the committee recommended for grant of approval for the proposed revision in prescribing information dated 12.01.2024 as presented by the firm.
9.	BIO/CT04/FF/ 2024/42660 Teclistamab solution for injection 30mg/vial (10mg/ml) & 153mg/vial (90mg/ml)	M/s. Johnson & Johnson Pvt. Ltd.	The firm presented the proposal for Phase IV clinical trial for Teclistamab solution for injection 30mg/vial (10mg/ml) & 153mg/vial (90mg/ml) titled “An open label, Multicenter, Phase IV study of Teclistamab to evaluate its safety in Indian Participants with Relapsed and Refractory Multiple Myeloma who have previously received at least 3 prior lines of therapy including an Immunomodulatory agent,

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			a Proteosome inhibitor and an Anti-CD38 antibody and have demonstrated disease progression on the last therapy" vide Protocol No. 64007957MM4007 dated 06 Feb, 2024. After detailed deliberation, the committee recommended the firm to conduct Phase IV study in minimum of 75 subjects and to submit interim report within one year for continuation of the approval.