

Recommendations of the SEC (Oncology) made in its 12th/25_{meeting} held on 09.04.2025_{at} CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/23/25 Online Submission (48116) Dostarlimab	M/s GSK Pharma India Private Limited	The firm presented phase III clinical study Protocol no.: 219606 amendment 4, dated 22-AUG-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/151/23 Online Submission (37946) AZD5305	M/s Astrazeneca Pharma India Limited	The firm presented Protocol Amendment Version 5.0 dated 29 Nov 2024 Protocol no. D9723C00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/24/25 Online Submission (48238) Trastuzumab Deruxtecan (T-DXd; DS-8201a) Rilvegostomig (AZD2936)	M/s Astrazeneca Pharma India Limited	The firm presented phase III clinical study Protocol no.: D781PC00001 CSP version no. 3.0 dated 29-Nov-2024 and Local CSP - Addendum IND, Version 1.0 dated 24 Dec 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. (Dr. Kaushal Kalra didn't participate)
Biological Division			
4.	BIO/CT18/FF/2025/4 7414 FDC of Nivolumab and Relatlimab 240mg/80 mg in 20 ml concentrate for solution for infusion	M/s Bristol-Myers Squibb India Pvt. Ltd.	The firm presented the proposal for grant of permission to import and market FDC of Nivolumab and Relatlimab 240mg/80 mg in 20 ml concentrate for solution for infusion for the indication i.e. "For the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma." with request for local clinical trial waiver based on the data generated from global clinical trial. The committee noted that the proposed FDC product is approved in countries including USA, EU, Australia, Canada. The committee noted that the proposed indications comes under the category of Orphan Drug and also there is an unmet medical need in the country. After detailed deliberation, the committee recommended for the grant of permission

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			to import and market the drug with waiver of local clinical trial with the condition to conduct Phase-IV clinical trial in India in the proposed indications. Accordingly, firm shall submit Phase IV Clinical Trial protocol to CDSCO within 03 months of grant of marketing authorization.
5.	BIO/CT18/FF/2024/4 5896 Trastuzumab Deruxtecan Powder for Concentrate for solution for infusion 100 mg	M/s AstraZeneca Pharma India Limited	<p>The firm presented the proposal for approval of addition indication for the drug Trastuzumab Deruxtecan Powder for Concentrate for solution for infusion 100 mg for the indication i.e. "Use of T-Dxd for the treatment of adult patients with unresectable or metastatic HER2-low (IHC 1+ and IHC 2+/ISH-) or HER2-ultralow (IHC0 with membrane staining) BC, who have received at least one endocrine therapy in metastatic setting" based on the results of the global clinical study conducted in proposed indication where India is a part of the study.</p> <p>The committee noted that the proposed indication is approved in countries including USA, EU, Japan, Australia and Canada. The committee further noted that there is an ongoing Phase IV study in India.</p> <p>After detailed deliberation, the committee recommended for approval of additional indication.</p>
6.	E-65288 Atezolizumab Injection 1200mg/20mL vial	M/s Roche Products (India) Pvt. Ltd.	<p>The firm presented the proposal to conduct a observational study titled "Real-World Indian Study Of Atezolizumab in Lung Cancer" vide Protocol No.: ML45036 Version No.: 2.0 dated 11.11.2024</p> <p>After detailed deliberation, the committee recommended for approval to conduct the study as per protocol presented by the firm.</p>
7.	E-51467 Teclistamab solution for injection 30 mg/vial (10mg/mL), 153mg/vial	M/s. Johnson & Johnson Pvt Ltd	<p>The firm presented the proposal for the revision in prescribing information based on EU SmPC dated 30.05.2024 and 11.07.2024 for Teclistamab Solution for Injection 30 mg/vial (10mg/ml) & 153 mg/vial (90mg/ml) with respect to</p>

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	(90mg/mL)		changes in Posology and method of Administration, special warning and precautions for use, Undesirable effects, Pharmacological properties, etc. After detailed deliberation, the committee recommended for approval of proposed revision in prescribing information dated 22.07.2024 as presented by the firm.
New Drug Division			
8.	ND/CT/25/000013 Nelarabine Injection 250 mg/50ml	M/s. Zydus Lifesciences Limited	The firm presented the proposal for grant of permission to conduct phase IV clinical trial with new drug Nelarabine Injection 250 mg/50ml before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct Phase IV clinical trial with the following changes- <ol style="list-style-type: none"> To include 25% of pediatric patients. To include stringent Complete response in secondary end point based on MRD less than 0.01% by flow cytometry. To include more Clinical Trial sites with pediatric oncologists. <p>Accordingly, the firm should submit revised Phase IV clinical trial protocol to CDSCO.</p>
9.	ND-11011(15)/18/2024-eoffice Darolutamide 300 mg film coated Tablets (NUBEQA)	Bayer Pharmaceuticals Pvt. Ltd.	The firm presented proposal for revision of Prescribing Information of drug Darolutamide 300 mg film coated Tablets as per the CCDS version 6, before the committee. After detailed deliberation, the committee recommended for grant of approval for revision of Prescribing Information of Darolutamide 300 mg film coated Tablets (NUBEQA), as presented by firm.
10.	ND-11011(15)/15/2024-eoffice Entrectinib Capsules 100mg/ 200mg	Roche Products India Pvt. Ltd.	The firm presented proposal for update in Package Insert (Version 3 & 4), before the committee. After detailed deliberation, the committee recommended for grant of approval for update in Package Insert of drug

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			Entrectinib Capsules 100mg/ 200mg, as presented by firm.