

Recommendations of the SEC (Oncology)) made in its 06th/24 meeting held on 19.03.2024 & 20.03.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/151/22 Online Submission (34938) KRC-01	M/s. Prorelix Service	In light of earlier SEC recommendation dated 07.12.2023 & 08.12.2023, the firm presented Phase-I/II clinical trial protocol along with published literature/academic research data before the committee. The firm informed the committee that the study protocol is approved in UK and Thailand for locally advanced cervical cancer. After detailed deliberation, the committee recommended that the firm should submit the Phase-I/II clinical trial report for the indication locally advanced cervical cancer for further review by the committee.
2.	CT/158/22 Online Submission (33905) Pralsetinib Capsules 100mg Entrectinib Capsules 100mg and 200mg Alectinib Capsule 150mg Durvalumab vial 500mg/10ml	M/s. Roche Products	The firm presented Phase I-III clinical study protocol No. BQ42777 version 3.0 dated 15 August 2023. After detailed deliberation, the committee recommend that the firm should submit more clarification for study rationale for comparing Alectinib with Durvalumab in cohort A1 for further review by the committee.
Biological Division			
3.	BIO/CT04/FF/2023/3 9652 Lyophilized Recombinant L- asparaginase-II for Injection 10000IU	M/s. Genova Biopharmaceuticals Limited	In light of the earlier SEC recommendation dated 07.12.2023 the firm presented the revised clinical trial protocol to conduct Phase I clinical trial titled "A double blinded, balanced, randomized, single dose, parallel group, active-controlled study to compare the pharmacokinetics of the test product GBL19 (recombinant asparaginase, Genova Biopharmaceuticals Ltd.) with the reference product Spectrila® (Medac GmbH) at 5000 IU/m ² , in healthy, adult subjects" vide protocol number version-01, dated 01/02/24.

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			After detailed deliberation, the committee recommended for grant of approval to conduct the clinical study as per the protocol presented by the firm with subject to condition that the firm shall submit safety data of first 20 subjects/first two cohorts enrolled in the study for evaluation by the committee and further continuation of the study.
4.	BIO/CT18/FF/2023/4 1177 Toripalimab 240mg solution for infusion	M/s. Dr. Reddy's Laboratories Limited	The firm did not turn up for presentation
5.	BIO/CT04/FF/2023/4 0241 Trastuzumab deruxtecan concentrate solution for infusion 100 mg/5 ml	M/s. Astra Zeneca	The firm did not turn up for presentation
6.	BIO/CT18/FF/2024/4 1456 Durvalumab 120 mg/2.4 mL and 500 mg/10 mL solution for infusion	M/s. Astra Zeneca	<p>The firm presented the proposal for approval of additional indication i.e., "Durvalumab (IMFINZI) in combination with chemotherapy as neoadjuvant treatment, followed by IMFINZI as monotherapy after surgery, is indicated for the treatment of patients with resectable (tumours \geq 4 cm and/or node positive) NSCLC and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements" based on the global clinical trial conducted including subjects from India.</p> <p>The committee noted that the proposed indication is not yet approved by any regulatory authorities. Also Phase IV study of the drug is ongoing in India for the approved indication i.e., locally advanced, unrescetable non-small cell lung cancer (NSCLC) and urothelial cancer".</p> <p>After detailed deliberation, the committee recommended the firm to submit 1) subset analysis of clinical data of Asian</p>

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			<p>population and Indian population of Global clinical study(AEGEAN) conducted in the proposed indication.</p> <p>2) Results of ongoing Phase IV clinical study</p> <p>3) Status of regulatory approval of the proposed indication for further evaluation.</p>
7.	<p>BIO/CT04/FF/2023/4 1012</p> <p>Pegfilgrastim</p>	M/s. CuraTeQ	<p>The firm presented the clinical study protocol to conduct Phase I clinical trial titled “Single dose study to compare pharmacokinetic, pharmacodynamic, immunogenicity and safety of Pegfilgrastim (BP14 Auto injector) injection 6 mg/ 0.6 mL and US-Licensed Neulasta® (pegfilgrastim) injection 6 mg/ 0.6 mL in healthy adult male subjects” vide protocol number C1B03750 (sponsor protocol No. BP14-103); version No.: 01 dated December 08, 2023.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per protocol presented by the firm.</p>
8.	<p>BIO/CT18/FF/2023/3 9717 (E-13800)</p> <p>Atezolizumab Injection (1875MG/15ML vial)</p>	M/s. Roche Products India Pvt. Ltd.	<p>In light of the earlier SEC recommendation dated 09.01.2024, the proposal of the firm has been re-deliberated 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 clinical trial waiver under unmet need in India and commitment to conduct Phase IV study.</p> <p>After detailed deliberation, the committee recommended the following.</p> <ol style="list-style-type: none"> 1. The firm should submit the global regulatory status of the drug for IV and SC route of administration along with indication wise. 2. The firm should clarify the reason for withdrawal of

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			<p>indications by USFDA along with its current status.</p> <p>Accordingly, the firm should submit the above clarifications to CDSCO for further evaluation by the committee.</p>
SND Division			
9.	<p>SND/MA/23/000028</p> <p>Abiraterone Acetate Oral Suspension 1000mg/5ml</p>	<p>M/s. BDR Pharmaceutical Int Private Limited</p>	<p>In light of earlier SEC recommendations dated 07.02.2024 & 08.02.2024. Now, the firm presented justification for waiver of Phase III clinical trial before the committee.</p> <p>The firm has informed that the proposed drug formulation Abiraterone Acetate Oral Suspension 1000mg/5ml not yet approved anywhere.</p> <p>The committee opined that the proposed formulation does not comes under CT waiver criteria i.e. unmet medical need, orphan drug status or indicated serious life threatening disease.</p> <p>After detailed deliberation, the Committee reiterated with their earlier recommendations to conduct Phase III clinical trial.</p> <p>Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review by the committee.</p>
10.	<p>SND-16011 (11)/8/2024-e-office</p> <p>Fulvestrant solution for injection 250mg/5ml (Faslodex)</p>	<p>M/s. Astrazeneca Pharma Pvt. Ltd.</p>	<p>The firm presented their proposal for updation in package insert of Fulvestrant solution for injection 250mg/5ml (Faslodex) with respect to proposed changes in posology and method of administration, contraindications, special warning condition and precautions for use, Pharmacodynamic & Pharmacokinetic properties and preclinical safety data before the committee.</p> <p>After detailed deliberation, the Committee recommended for updation of proposed changes in package insert with the condition that the firm should submit the copy of approval from county of origin for such PI update.</p>

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11.	SND/MA/23/000286 Letrozole Oral Suspension 2.5mg/5ml (Additional dosage form)	M/s. Beta Drugs Limited	<p>The firm presented their proposal for grant of permission to manufacture and marketing of Letrozole Oral Suspension 2.5mg/5ml (Additional dosage form) along with justification for waiver of Phase III clinical trial and bioequivalence study protocol before the committee.</p> <p>The committee noted that the proposed formulation “Letrozole Oral Suspension 2.5mg/5ml” not approved in anywhere.</p> <p>After detailed deliberation, the committee opined that the firm should to conduct BE study as per protocol presented by the firm and submit the BE report for further consideration of Phase III clinical trial.</p>
12.	SND-16011 (11)/21/2024-e-office Osimertinib Tablets 40 mg and 80 mg	M/s. Astrazeneca Pharma Pvt. Ltd.	<p>The firm presented their proposal for updation in package insert of Osimertinib tablets 40mg and 80mg (Tahrisso) with respect to proposed changes in Undesirable effects, special warning and special precautions for use, and Pharmacodynamic properties before the committee.</p> <p>After detailed deliberation, the committee recommended for updation of proposed changes in package insert with the condition that the firm should submit the copy of approval from county of origin for such PI update.</p>
13.	SND-12012/1/2024-eoffice Olaparib film coated Tablets 100mg & 150mg for additional Indication	M/s. Astrazeneca Pharma India Limited	The firm did not turn up for presentation
New Drugs Division			
14.	ND/IMP/22/000015 Selpercatinib 40 mg & 80 mg	M/s. Eli-Lilly	<p>In continuation to earlier SEC recommendations dated 11.07.2023, the firm presented its proposal for grant of permission to import and market Selpercatinib Capsule 40mg & 80mg along with the Phase IV clinical trial waiver before the committee.</p> <p>After detailed deliberation, the committee</p>

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			<p>recommended for grant of permission to import and market Selpercatinib Capsule 40mg & 80mg for the indication:</p> <ul style="list-style-type: none"> • Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC). • Adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy. • Adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate) <p>However, the committee did not recommend Phase IV clinical trial waiver. Accordingly, the firm should submit Phase IV Clinical Trial protocol within 3 months of approval for further consideration by the committee.</p>
15.	12-78/2010-DC Degarelix Injection	M/s. Ferring	The firm did not turn up for presentation
16.	12-7/18-DC Olaparib Tablets 100 mg and 150 mg	M/s. Astrazeneca	<p>The firm has presented the clinical evidence for the withdrawal of indication of Olaparib 100mg and 150 mg tablets in the treatment of patient with gBRCA mutation and advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.</p> <p>After detailed deliberation, the Subject expert committee has agreed for withdrawal of same indication.</p>