

Recommendations of the SEC (Oncology) made in its 11th/25 meeting held on 02.04.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2024/43082 Pembrolizumab	M/s MSD Pharmaceutical Pvt. Ltd.	In light of the earlier SEC recommendation dated 07.08.2024 & 08.08.2024 for approval of additional indications of Non small cell lung carcinoma (Monotherapy and combination therapy), the firm presented the safety data from Phase-IV study (KEYNOTE-593) conducted in Indian patients. The committee noted that proposed additional indications are approved in 55 countries including USA, EU, Canada, Australia etc. The committee noted that drug falls under orphan drug category for the proposed additional indications. Further there is unmet medical need for the treatment of proposed indications. After detailed deliberation the committee recommended for approval of additional indications with condition to conduct Phase-IV study in the proposed indications in India. Accordingly, the firm shall submit Phase IV study protocol to CDSCO within 3 months of approval of additional indications.
2.	BIO/CT21/BO/2024/46843 Trastuzumab 150mg/440mg (PGS formulation)	M/s. Biocon Biologics Ltd	The firm did not turn up for the presentation.
New Drugs Division			
3.	ND/IMP/24/000030 Ivosidenib 250 mg film-coated tablet	M/s Servier India Private Limited	In light of earlier SEC recommendation dated 10.12.2024 wherein firm was recommended to conduct PK/PD study protocol in Indian population by the committee. The firm has re-deliberated their proposal alongwith the justification for the waiver of PK/PD study in Indian population. The firm has presented the PK/PD data of Ivosidenib in Asian Vs. non Asian populations. The firm also presented

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			<p>Phase III PK/PD subset analysis and demonstrated similarity across diverse ethnicity.</p> <p>The committee noted that there is unmet medical need in country.</p> <p>After detailed deliberation, the committee recommended for the grant of permission for the import and marketing of the drug Ivosidenib 250 mg film-coated tablet with waiver of PK/PD study and Phase III clinical trial with condition that the firm should conduct Phase IV clinical trial for which the protocol should be submitted within 3 months of approval of the drug for review by the committee</p>
SND Division			
4.	SND/16011(11)/25/20 25 e-office Receipt no. 58434	M/s AstraZeneca Pharma India Limited	The firm didn't turn up for presentation.
5.	SND/IMP/24/000117 Selpercatinib Tablets 40mg, 80mg, 120mg and 160mg (Additional indication and additional strength)	M/s Eli Lilly	<p>The firm presented the proposal for grant of permission to import and marketing of the drug Selpercatinib Tablets 40mg, 80mg, 120mg and 160mg for additional indication, additional strength and new dosage form along with Global BE study (J2G-MC-JZJZ) for 160 mg tablet, food effect study (J2G-MC-JZPA) results (Global study where Indian Patients not participated) and ongoing Phase III study LIBRETTO-531 (05 Indian patients participating) before the committee.</p> <p>The Committee noted that CDSCO has already approved Selpercatinib Capsules 40 mg & 80 mg. The Committee also noted that Selpercatinib, an orphan drug, approved in key countries i.e. US, EU, UK, Canada, Australia etc.</p> <p>After detailed deliberation, the Committee recommended for import and marketing of Selpercatinib Tablets 40mg, 80mg, 120mg and 160mg for Proposed strength and indication with the condition to conduct Phase IV clinical trial.</p>

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			Accordingly, firm should submit the Phase IV Protocol to CDSCO with 03 months of approval for review by the committee.
6.	SND/CT/24/000102 Mercaptopurine Powder for Oral Suspension 10 mg/mL	M/s IDRS Labs Private Limited	The firm presented the proposal for grant of permission to conduct Phase IV clinical trial vide protocol No. IDRS/CT/6MP/001/2024 Version 1.0 dated 17.07.2024 before the committee. After detailed deliberation, the committee recommended for approval to conduct the study as per the protocol presented by the firm.
7.	SND/MA/21/000082 Triptorelin Powder for Injection 22.5 mg	M/s Dr. Reddy's Laboratories Limited	The committee requested to the firm to deliberate their Proposal for additional indication in SEC (Endocrinology).
8.	SND/MA/23/000061 Methotrexate Oral Solution 2mg/mL	M/s Beta Drugs Ltd	In light of earlier SEC recommendation dated 11.02.2025, the firm has presented BE study protocol BN25-008 Ver. 00 dated 12-Mar-2025 in fed condition before the committee. After detailed deliberation, the committee recommended for the grant of permission to conducted the BE Study as per the fed protocol presented by the firm. Accordingly, firm should submit the fed BE study report to CDSCO for further review by the committee.