Recommendations of the SEC (Oncology) made in its 22th/25 meeting held on 08.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/25/000029 Sotorasib tablet 240 mg	M/s Amgen Technology Pvt. Ltd	The firm presented the proposal for grant of permission for Import and Marketing of the drug Sotorasib tablet 240 mg along with justification for local Phase III Clinical Trial waiver before the committee. The firm has presented the interim study report of ongoing Phase III Global Clinical Trial data for safety and efficacy of drug which also included data on Asian patients. The committee noted that the drug is approved in around 55 countries including US, Australia, Canada, EU and Japan. The Committee reviewed the data and the interim Phase III Clinical Trial report and noted that the KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC) in adults as an unmet medical need. After detailed deliberation, the committee recommended for the grant of permission for the import and marketing of the drug Sotorasib tablet 240 mg with waiver of 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. The Committee also recommended that the drug should be prescribed by Medical Oncologist only.
2.	ND/CT/25/000031 Brigatinib Tablet 30 mg, 90 mg, 180 mg	M/s Takeda Biopharmaceuticals Ltd.	In line with the condition of permission for import and marketing of the drug Brigatinib Tablets 30 mg/ 90 mg/ 180 mg, the firm presented Phase IV clinical trial protocol before the committee.

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			The committee noted that proposed Phase IV Clinical Trial is a non-interventional study. Therefore, the committee recommended that firm should submit structured Phase IV Clinical trial protocol preferably with comparator within one month to CDSCO for further review by the committee.