

Recommendations of the SEC (Radio-diagnostics) made in its 04th/25 meeting held on 23.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/21/000084 Mon.LUTEC 37 GBq/mL radiopharmaceutical precursor solution (Lutetium chloride solution for Injection)	M/s. Syphen Technologies	<p>In light of earlier SEC recommendation dated 07.11.2025, the firm presented the proposal for grant of permission to Import and Market of new drug, Mon.LUTEC 37 GBq/mL (Lutetium chloride solution for Injection) radiopharmaceutical precursor solution along with revised package insert before the committee.</p> <p>The committee noted that the drug is approved in various countries including India, US, Europe, Turkey etc.</p> <p>The Committee noted that the product is used in country since 2021 for neuroendocrine tumors, prostate cancer and bone pain palliation.</p> <p>After detailed deliberation, the committee recommended for the grant of permission for the Import and Marketing of the drug, Lutetium chloride solution for Injection 37 GBq/ml only as a radiopharmaceutical precursor solution and not intended for direct use in patients and to be used only for the radiolabeling of carrier molecules that have been specifically developed and authorized for radiolabeling with Lutetium (Lu 177) chloride subject to the condition that firm should conduct PMS for which protocol should be submitted to CDSCO within 3 months from date of approval for further review by the committee.</p> <p>Further, firm should submit PSUR data generated on Indian population to CDSCO.</p>
SND Division			
2.	SND/IMP/24/000008 IOHEXOL INJECTION 300.000 mgI/ml & IOHEXOL INJECTION 350 mgI/ml	M/s. Wipro GE Healthcare Pvt. Ltd.	<p>Firm presented the proposal for the import and marketing of the already approved product for the additional Indication.</p> <p>The firm also presented the global approval status along with published data on Contrast-enhanced Spectral Mammography (CSEM).</p>

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			The committee noted that the proposed technology (CESM) has advantage over existing CEM technique. After detailed deliberation the committee recommended for grant of permission with local CT wavier.