

Recommendations of the SEC (Radio-Diagnostic) made in its 03th/25 meeting held on 07.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/IMP/25/000083 Iopromide Injection U.S.P. 0.623 grams (g) and Iopromide Injection U.S.P. 0.769 grams (g)	M/s Bayer Pharmaceuticals Pvt. Ltd.	<p>The firm presented the proposal for grant of permission for import and marketing Iopromide Injection U.S.P. 0.623 gm & 0.769 gm for additional indication along with justification for clinical trial waiver before the Committee.</p> <p>The committee noted that the product is approved in India from 1990 and the applied drug formulation approved in USA and other key countries for indication as Contrast mammography to visualize known or suspected lesions of the breast in adults, as an adjunct following mammography and/or ultrasound.</p> <p>After detailed deliberation, the Committee recommended for grant of permission to import and market Iopromide Injection U.S.P. 0.623 gm & 0.769 gm with CT waiver for indication as Contrast mammography to visualize known or suspected lesions of the breast in adults, as an adjunct following mammography and/or ultrasound.</p> <p>Accordingly, firm should submit the revised Package insert to CDSCO for further review.</p>
2.	SND/IMP/24/000008 IOHEXOL INJECTION 300.000 mgI/ml & IOHEXOL INJECTION 350.000 mgI/ml	M/s Wipro GE Healthcare Pvt. Ltd	The firm did not turn up for the presentation.
New Drugs Division			
3.	ND/IMP/21/000084 Mon. LUTEC 37 GBq/mL radiopharmaceutical precursor solution (Lutetium chloride	M/s Syphen Technologies	The firm presented the proposal for grant of permission to import and market of new drug, radiopharmaceutical precursor solution, Lutetium chloride solution for Injection 37 GBq/mL before the committee.

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	solution for Injection)		<p>The committee opined that the firm should specify that proposed drug product is not intended for direct use in patients and it is to be used only for radio labelling of carrier molecules that have been specifically developed and authorized for radio labeling with lutetium (¹⁷⁷Lu) chloride and submit the revised package insert in line with internationally approved indication to the committee for further review.</p> <p>The committee further noted that experts from AERB and nuclear medicines specialty should be invited in the next review by the committee</p>