

Recommendations of the SEC (Radio-Diagnostic) made in its 13th meeting held on 27.04.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/21/000014 Kit for the Preparation of Technetium (99mTc) Sestamibi Injection 1 mg	M/s. IBA Molecular Imaging	<p>The firm presented the proposal for import and marketing of the drug Kit for the preparation of Technetium (99mTc) Sestamibi for Injection 1mg.</p> <p>The committee noted that the product is approved in more than 30 countries and also imported into India. The safety of the drug is well established and there is no safety signal received with the use of the drug globally.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and marketing of the drug “Kit for the preparation of Technetium (99mTc) Sestamibi for Injection 1mg.”</p>
2.	ND/CT/22/000072 Multi-Hance (Gadobenatedimeglumine) 0.5 M solution for Injection	M/s. Imaging Products India Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 22.09.2021, the firm presented the proposal for conduct of active surveillance study protocol No- OBS-BII-002, final version, dated 01.08.2022 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed active surveillance study as per the protocol presented.</p>
3.	ND/IMP/21/000084 Mon. LUTEC 37 GBq/ml radiopharmaceutical precursor solution (Lutetium chloride solution for Injection)	M/s. Syphen Technologies	The firm did not turn up for presentation.