

**Recommendations of the SEC (Radio-Diagnostic) made in its 02<sup>th</sup> meeting held on 26.09.2024 at CDSCO HQ New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Medical Devices Division</b>			
1.	IMP/MD/2023/110413  Breast ultrasound imaging system (Brand Name: INVENIA ABUS 2.0)	M/s. Wipro GE Healthcare Private Limited	<p>The firm presented proposal for grant of permission to import and market the medical device viz. Breast ultrasound imaging system- “INVENIA ABUS 2.0” under form MD-27 manufactured by M/s GE Parallel Design Inc., United States.</p> <p>The firm presented the clinical evaluation report carried out in USA &amp; EU. The approval of device in USA, Australia, Canada are also produced and claimed that it is available in their market since year 2018.</p> <p>After detailed deliberation and based on the documents presented, the committee recommended for consideration of the proposal with the condition that the firm shall conduct Post Marketing Clinical Investigation to have a clinical effectiveness data in Indian population.</p> <p>Accordingly, the firm shall submit a study protocol within a period of six months from date of launch of the product in the country.</p>
<b>New Drugs Division</b>			
2.	ND/CT/20/000111  ProHance (Gadoteridol Injection 279.300 mg/ml)	M/s. Imaging Products India Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 22.09.2021 and as per condition of Form CT-20 dated 29.07.2021, the firm presented Phase IV clinical trial report before the committee.</p> <p>After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.</p>
3.	12-01/17-DC (Pt-79)  OMNISCAN (Gadodiamide)	M/s. Wipro GE healthcare Pvt. Limited	<p>In light of earlier SEC recommendation dated 22.09.2021 and subsequent NOC dated 13.10.2021 issued by this office, the firm presented report on Active Surveillance of the safety of OMNISCAN (gadodiamide) before the committee.</p> <p>After detailed deliberation, the committee noted and agreed to the result of the Active Surveillance study.</p>

