5. Refurbished Medical Devices in India – S & T

Refurbished Medical Devices

Refurbished medical devices are previously used medical systems that are restored to their original manufacturer specifications, tested for safety and functionality, and resold at a substantially lower price than new equipment. These devices typically include capital-intensive, high-technology machines used in advanced diagnostics, imaging, and surgical procedures.

Refurbishment may involve

1. Replacement of worn-out components
2. Software upgrades
3. Calibration and revalidation
4. Cosmetic restoration
5. Quality assurance testing

Common examples include-

1. MRI (Magnetic Resonance Imaging) scanners
2. CT (Computed Tomography) scanners
3. PET-CT systems (Positron Emission Tomography–CT)
4. Advanced endoscopy and laparoscopy systems
5. Robotic navigation and robotic surgery platforms

Refurbished devices are typically sourced from developed markets such as the United States, Germany, Japan, and the Netherlands, where hospitals upgrade equipment before the end of its full functional lifespan.

Why Cost Matters- Economic Rationale- High-end diagnostic and surgical machines require significant capital investment, which directly influences healthcare access in smaller cities and rural regions.

Price Comparison

1.5 Tesla MRI

1. New price- ₹4–8 crore
2. Refurbished price- ₹1–3.5 crore

PET-CT

1. New price- About ₹20 crore
2. Refurbished price- ₹60 lakh–₹3.5 crore

CT Scanner

1. New price- ₹2–4 crore
2. Refurbished price- ₹20 lakh–₹2.5 crore

Implications- For Tier-2 and Tier-3 cities, district hospitals, and standalone diagnostic centres, the price difference determines whether advanced imaging facilities are locally available.

Lower capital costs improve

1. Geographic equity in healthcare access
2. Diagnostic capacity in underserved regions
3. Reduction in patient travel costs
4. Faster disease detection and treatment

Refurbished devices may therefore play a critical role in expanding universal health coverage.

Current Regulatory Landscape in India

Absence of a Dedicated Regulatory Pathway- India currently does not have a specific regulatory framework governing refurbished medical devices under the Medical Devices Rules, 2017. In 2020, all medical devices were notified as 'drugs' under the Drugs and Cosmetics Act, expanding central oversight. However, no distinct licensing pathway was created for refurbished devices.

This creates ambiguity regarding

1. Market approval
2. Safety certification
3. Sale and distribution

Import Framework- Environmental Route- Imports of used medical equipment are primarily governed under the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016.
Amendments (December 2022)- Certain high-end used devices are permitted for import.
Prior approval from the Ministry of Environment, Forest and Climate Change (MoEFCC) is required.
Applicants must submit

1. Maintenance history
2. Quality assurance reports
3. Compliance documentation

Technical input from the Central Drugs Standard Control Organisation (CDSCO) is required. Import authorisation from the Directorate General of Foreign Trade (DGFT) is mandatory. This framework treats refurbished devices primarily as waste management and environmental compliance issues rather than medical safety regulation issues.
Regulatory Conflict and Legal Inconsistency- In January 2025, CDSCO stated that refurbished devices cannot be imported for sale or distribution because there is no licensing provision under the Medical Devices Rules. In November 2025, a technical expert committee under MoEFCC cleared several refurbished devices for reuse, including CT scanners, MRI systems, and robotic surgical platforms.
This created a regulatory inconsistency

1. MoEFCC approval under environmental rules
2. CDSCO prohibition under medical device laws

The conflict highlights a lack of inter-ministerial regulatory alignment between environmental regulation and healthcare regulation.
Import Dependency and Structural Challenges
India remains dependent on imports for high-end imaging technologies due to-

1. Precision engineering requirements
2. Advanced detector technologies
3. Complex embedded software systems
4. Sophisticated global supply chains

Domestic manufacturing capacity for high-end imaging remains limited. Refurbished imports partially bridge this technology gap but raise strategic questions about long-term industrial policy.
New Policy Committee (February 2026)- The Ministry of Health and Family Welfare has constituted a committee to develop a formal policy framework on refurbished medical devices.
Committee Mandate- • Define what qualifies as 'refurbished' versus 'used' or 'obsolete'.
Develop standardised evaluation mechanisms for

1. Safety
2. Performance
3. Remaining useful life

Recommend waste disposal and end-of-life management guidelines. Examine regulatory harmonisation between Medical Devices Rules and environmental laws. Propose a licensing and compliance pathway. This signals recognition of the need for regulatory clarity.

Stakeholder Perspectives

International Manufacturers (MTAI)- The Medical Technology Association of India (MTAI), representing international companies, argues. A blanket ban would reduce affordability and access.
India requires a globally aligned and time-bound regulatory policy. Refurbished devices should be permitted only through original equipment manufacturers (OEMs) to ensure

1. Legal accountability
2. Proper servicing
3. Availability of spare parts
4. Patient safety safeguards

They argue refurbished devices

1. Expand access in smaller cities
2. Support healthcare workforce training

3. Strengthen India's medical tourism and healthcare export ambitions

Domestic Manufacturers (AiMeD)- The Association of Indian Medical Device Industry (AiMeD) raises concerns- Usage history may be incomplete or unverifiable. Performance consistency and calibration reliability may vary. Limited traceability may increase liability risks. Shorter remaining lifespan may create hidden long-term costs. India risks becoming a dumping ground for obsolete technology. Liberal imports could undermine 'Make in India' objectives and weaken domestic manufacturing incentives. Overdependence on imports may compromise preparedness during health emergencies.

Key Policy Dilemmas-

Balancing affordability with patient safety. Promoting domestic manufacturing versus ensuring immediate access to advanced technology. Harmonising environmental regulations with medical device safety standards. Ensuring accountability in refurbishment quality. Preventing dumping of obsolete or unsafe equipment.

Way Ahead- Policy Imperatives- The policy committee must address multiple dimensions

Legal Clarity- Establish a clear statutory definition of refurbished medical devices. Create a licensing pathway under the Medical Devices Rules. Harmonise CDSCO regulations with MoEFCC waste management rules.

Quality and Safety Standards- Define mandatory testing protocols. Specify certification requirements. Establish minimum remaining lifespan criteria. Mandate traceability and maintenance documentation. Ensure OEM-backed servicing and warranty obligations.

Transparency and Consumer Protection- Require clear disclosure of refurbishment status to buyers and patients. Create a public registry of approved refurbished devices. Strengthen post-market surveillance and adverse event reporting.

Industrial Strategy Alignment- Integrate refurbished device policy with-

1. Make in India
2. Production Linked Incentive (PLI) schemes
3. Domestic R&D capacity building

Encourage domestic refurbishment industry under strict compliance norms.

Environmental Safeguards- Mandate responsible end-of-life disposal. Prevent accumulation of electronic medical waste. Align with circular economy objectives.

Strategic Significance- The final policy outcome will influence. India's diagnostic infrastructure expansion. Healthcare affordability in smaller cities. The trajectory of domestic medical device manufacturing. India's long-term ambitions in global medical technology value chains. Regulatory coherence between environmental, trade, and health ministries.

Conclusion- Refurbished medical devices represent both an opportunity and a regulatory challenge for India. They can significantly expand affordable diagnostic access but raise concerns about safety, industrial competitiveness, and regulatory consistency.

A carefully designed framework that balances patient safety, industrial policy, environmental responsibility, and healthcare access will determine whether refurbished devices become a bridge to healthcare equity or a source of systemic vulnerability.

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