

Refurbished Medical Devices

Prelims: Current events of national and international importance | Health

Why in News?

Recently, the Ministry of Health and Family Welfare has formed a committee to frame a policy for refurbished medical devices amid a dispute between domestic and global manufacturers.

- **Refurbished medical devices** - They are pre-used equipment restored to original operating specifications and resold at a lower cost.
 - They are capital-intensive technologies.
- **Components** - Includes high-end systems like MRI, CT scanners, PET-CT systems, robotic surgery systems, endoscopy and laparoscopy equipment.
- **Procurement Cost** -

| Device | New (Rs crore) | Refurbished (Rs crore) |
|-------------------|----------------|------------------------|
| MRI (1.5T) | 4 - 8 | 1 - 3.5 |
| PET-CT | 20+ | 0.6 - 3.5 |
| CT Scanner | 2 - 4 | 0.2 - 2.5 |

- Lower cost helps hospitals in Tier-2, Tier-3 cities and standalone diagnostic centres.
- **Regulatory Framework - Medical Devices Rules, 2017** - No dedicated regulatory pathway for refurbished medical devices.
- **Drugs and Cosmetics Act, 2020** - Under which all medical devices are notified as “drugs”, but refurbished products are not separately defined.
- **Import Regulations** - Imports allowed through No-Objection Certificates (NOCs) issued by an expert committee under the Ministry of Environment, Forest and Climate Change (MoEFCC).
 - **Central Drugs Standard Control Organisation (CDSCO)** - Provides quality assurance and other reports.
 - **Directorate General of Foreign Trade (DGFT)** - Import authorisation.
- **Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016** - Primarily governs Imports of used medical equipment.
- **Status** - India has no legal definitions for “used”, “refurbished”, “reconditioned”, or “remanufactured” medical devices, causing regulatory ambiguity.
- **Expert concern** - Risk India becoming a dumping ground for outdated technology.

Reference

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