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- **Expert concern –** Risk India becoming a dumping ground for outdated technology.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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