

Reuse of Single-Use Medical Devices in India

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Why in News?

The Directorate General of Health Services (DGHS) has instructed all public and private healthcare facilities in India to cease the reuse of medical devices and disposable surgical items that are designated for single use.

Single-Use Medical Devices

- Medical devices are designed and labelled by the Original Equipment Manufacturer (OEM) for use on a patient during a single procedure or for a single use.
- These devices are intended to be discarded after use in accordance with the manufacturer's instructions.
- **Note** - Sterilisation does not automatically make a single-use device suitable for reuse.

Examples of devices reportedly reused

- **Cardiology** - Cardiac catheters and guidewires used in angiography and angioplasty procedures.
- **Nephrology** - Equipment related to dialysis procedures.
- **Surgery** - Selected surgical instruments and disposable surgical items.
- **Other devices** - Disposable syringes and needles.

Risks Associated with Reuse

Risk	Explanation
Cross-infection	Transmission of infections between patients.
Device malfunction	Reused devices may fail during medical procedures.
Reduced performance	Device effectiveness may decline after use or reprocessing.
Patient safety	Increased risk of complications, particularly in critical care.
Financial exploitation	Patients may be charged the full price for a device that has been reused.
Lack of informed consent	Patients may not be told that a device has been reused.

Legal and Regulatory Framework

The DGHS has highlighted possible violations of the following laws and requirements:

Law / Framework	Mandates
Drugs and Cosmetics Act, 1940	Legal framework governing drugs and specified medical-device regulatory matters.
Medical Devices Rules, 2017	Regulatory framework for medical devices in India, including their quality and safety.
Clinical Establishments (Registration and Regulation) Act, 2010	Provides for registration and regulation of clinical establishments; its applicability depends on the relevant jurisdiction.
Infection-control requirements	Measures to prevent healthcare-associated infections.
Biomedical Waste Management Rules, 2016	Govern the handling and disposal of biomedical waste.

Key Authorities and Their Responsibilities

- The Directorate General of Health Services (DGHS) issued a directive outlining associated risks and emphasising the need for enforcement.
- State and Union Territory health authorities are responsible for maintaining vigilance and monitoring healthcare establishments.
- State drug controllers are tasked with inspecting establishments and implementing appropriate regulatory actions.
- The Drugs Controller General of India (DCGI) serves as the central regulatory authority for medical device regulation.
- The Central Government Health Scheme (CGHS) has previously addressed this issue for hospitals empanelled under the scheme.

Recommended Measures for Effective Enforcement

The Association of Indian Medical Device Industry (AiMeD) welcomed the directive and recommended the following measures:

- Conducting regular inspections of healthcare facilities.
- Maintaining traceable records of medical device usage and disposal.
- Providing training to healthcare personnel on device safety.
- Establishing clear accountability for instances where devices are reused contrary to manufacturers' instructions.
- Taking action against hospitals that violate applicable regulations.
- Implementing measures to ensure that cost considerations do not encourage unsafe reuse of medical devices.

Issues and Challenges

- **Cost pressures** - Hospitals may reuse devices to reduce expenditures.
- **Weak monitoring** - Enforcement relies substantially on state and Union Territory authorities.
- **Patient awareness** - Patients may be unaware of whether a device has been reused.
- **Accountability gaps** - Responsibility for unauthorised reuse must be clearly enforced.
- **Implementation gap** - The directive does not specify a revised inspection schedule or

a distinct penalty for hospitals found reusing such devices.

Reference

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