GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. 1086
TO BE ANSWERED ON 24TH JULY, 2026

UNREGULATED SINGLE USE MEDICAL DEVICES

1086. SHRI AZAD KIRTI JHA:

Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the Government is aware of the instances of unregulated reuse of Single-Use Medical Devices (SUDs) in public and private healthcare centres across the country, despite labelling regulations under the Medical Devices Rules, 2017, if so, the details of such cases reported during the last five years, State/UT-wise and district-wise;

(b) whether there are any health and financial impacts on patients from such reuse, if so, the details thereof;

(c) the details of policies formulated by the Government to prevent unsafe SUD reuse and ensure ethical and safe practices;

(d) whether there are any existing procedures for obtaining informed consent regarding SUD reuse and whether patients are adequately informed of risks, if so, the details thereof;

(e) whether any complaints or representations have been received from patients, healthcare professionals or civil society regarding this practice and calls for guidelines, if so, the details thereof;

(f) the details of action taken/proposed to be taken by the Government against entities involved in such unregulated reuse;

(g) the steps contemplated by the Government to address patient safety, informed consent and care quality implications; and

(h) whether the Government has any plans to frame national guidelines or amend laws like the Drugs and Cosmetics Act or Clinical Establishments Act for clearer regulation in this regard, if so, the details thereof?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) to (h): Manufacture and import of Medical Devices are regulated under the provisions of the Medical Devices Rules, 2017. As per Rule 44 of the said Rules, manufacturers and importers are required to appropriately label a medical device, including where the device is intended for single use. Non-compliance with such labelling requirements constitutes an offence under the provisions of the Medical Devices Rules, 2017 and the Drugs and Cosmetics Act, 1940.

Central Drugs Standard Control Organisation (CDSCO) has not received any complaints or reported cases regarding unregulated reuse of Single-Use Medical Devices during the last five years.

The Government of India has enacted the Clinical Establishments (Registration and Regulation) Act, 2010 and notified Clinical Establishments (Central Government) Rules, 2012 for registration of Clinical Establishments with a view to prescribing the Minimum Standards of facilities and services provided by them. Under the said Act, the National Council for clinical establishments has approved Minimum Standards for different levels of Hospitals. As per these standards, the hospitals are also required to follow standard precautions like practicing hand hygiene, use of personal infection equipment etc. and infection control practices including compliance to Bio-Medical Waste Management Rules to reduce high risk of healthcare associated infection.

'Health' being a State subject, the States / UTs which have adopted the CE Act are primarily responsible for enforcing/implementing the provisions of the CE Act in the respective States/UTs. The Act also provides for cancellation of registration, if the provisions of the Act are not complied with.

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