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

RAJYA SABHA
UNSTARRED QUESTION NO. 1211
TO BE ANSWERED ON 10.02.2026

ANTIMICROBIAL RESISTANCE

1211. SHRI PRAMOD TIWARI:

Will the **MINISTER OF HEALTH AND FAMILY WELFARE** be pleased to state : -

(a) whether antimicrobial resistance has now become a major public health and economic threat;
(b) if so, the details thereof; and
(c) the steps proposed to be taken by Government for safe disposal of expired or unused antibiotics alongside inspections of manufacturing units to ensure compliance with bio-medical waste management rules?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE
(SHRI PRATAPRAO JADHAV)

(a) & (b) : The Government is aware of the growing challenge of Antimicrobial Resistance (AMR) in the country. To address this public health concern, the Government has taken a number of strategic and coordinated measures across sectors. The details of the steps taken are at Annexure-I.

(c): The Government has taken measures for safe disposal of expired or unused antibiotics and for ensuring compliance of manufacturing units with bio-medical waste management requirements. The steps taken include the following:

I. The Central Drugs Standard Control Organization (CDSCO) has issued a Guidance Document on Disposal of Expired/Unused Drugs providing a framework for environmentally safe and compliant disposal practices.
II. Under the amended Schedule M of the Drugs Rules, 1945 (notified vide GSR 922(E) dated 28.12.2023), specific provisions relating to bio-medical waste management and safe handling and disposal practices are mandated for licensed drug manufacturing units.
III. Regulation of manufacture and sale of drugs under the Drugs and Cosmetics Act, 1940 and Rules made thereunder is carried out through a system of licensing and periodic inspections by State Licensing Authorities appointed by the respective State Governments.
IV. Manufacturing premises are required to comply with licence conditions, including Good Manufacturing Practices (GMP) and prescribed waste management standards. State Licensing Authorities are empowered to take regulatory action in case of non-compliance.

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ANNEXURE

Details of steps taken by Government to contain Antimicrobial Resistance (AMR)

I. The Ministry of Health and Family Welfare has issued Standard Treatment Guidelines (STGs) for rational use of medicines, including antibiotics. These guidelines are available in the public domain on the NCDC website.

II. Guidelines on Infection Prevention and Control (IPC) have been issued to prevent and control healthcare-associated infections and to reduce unnecessary use of antibiotics in healthcare settings.

III. To promote judicious use of antibiotics and generate awareness on AMR, the National Centre for Disease Control (NCDC) has developed IEC materials including audio-visual content, social media messages and outdoor media campaigns. These materials are available in the public domain and have been shared with States/UTs for wider dissemination.

IV. The Indian Council of Medical Research (ICMR) has established an AMR surveillance and research network comprising 21 tertiary care hospitals. Antimicrobial Stewardship (AMS) programmes have been implemented in these hospitals, and each hospital has developed its own antibiotic policy. ICMR also supports multiple research projects covering basic, clinical and applied AMR research.

V. ICMR has issued Guidelines on Infection Control in Hospitals (2016) to facilitate hospitals in developing infection control programmes.

VI. The Central Drugs Standard Control Organization (CDSCO) regulates the safety, efficacy and quality of drugs under the Drugs and Cosmetics Act, 1940 and Rules made thereunder. Antibiotics are included under Schedule H and Schedule H1 and are required to be sold only on the prescription of a Registered Medical Practitioner.

VII. Amendment of the Drugs & Cosmetics Rules, 1945 (effective 01.03.2014) introduced Schedule H1 covering specified antibiotics, anti-TB and habit-forming drugs, with stricter labelling, prescription and record-keeping requirements.

VIII. Maintenance of separate sale registers for Schedule H1 drugs has been made mandatory, including prescriber and patient details, to be preserved for three years for inspection.

IX. CDSCO has issued various notices, advisories and communications to State Drug Regulators and other stakeholders for strict compliance with regulatory provisions and for curbing misuse of antibiotics.

X. States/UTs have been advised to promote prescription of generic medicines and to conduct regular prescription audits in public health facilities. Prescription audit is also one of the requirements under National Quality Assurance Standards (NQAS) certification.

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