

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

**LOK SABHA
UNSTARRED QUESTION NO. 2207
TO BE ANSWERED ON 31ST JULY, 2026**

MISUSE OF ANTIBIOTICS AND PACKAGING WARNINGS

†2207. DR. RAJKUMAR SANGWAN:

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

- (a) whether the Government has conducted any study to assess the adverse effects of antibiotic misuse in the country, if so, the details thereof along with the efforts being made for its prevention;
- (b) whether it is a fact that in the absence of clear warnings/symbols on the packaging of antibiotics in the country their inappropriate and excessive use is taking place, if so, the details thereof, State-wise; and
- (c) whether the Government proposes to mandate special coding, colour-coding, clear markings, warnings, or QR codes on the packaging, keeping in view the increasing misuse of antibiotics so that patients and pharmacists can identify the medicine, if so, the details thereof?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI PRATAPRAO JADHAV)**

(a) to (c): The Indian Council of Medical Research (ICMR) has informed that it conducted extensive surveillance studies to document the rising levels of antimicrobial resistance (AMR), through its Antimicrobial Resistance Surveillance and Research Network (AMRSN). This nationwide network monitors resistance patterns in major bacterial and fungal pathogens across multiple hospitals and has documented increasing resistance to commonly used antibiotics among organisms such as *E. coli*, *Klebsiella*, *Staphylococcus aureus* and other priority pathogens. The data on AMR in pathogens of public health importance is available on:

https://www.icmr.gov.in/icmrobject/uploads/Report/1763981012_icmramrsnannualreport2024.pdf

https://www.icmr.gov.in/icmrobject/uploads/Documents/1725536060_annual_report_2023.pdf

ICMR has further informed that in collaboration with Jai Prakash Narayan Apex Trauma Centre, All India Institute of Medical Sciences (AIIMS), Delhi, it has undertaken promotion on robust Infection Prevention and Control (IPC) practices in healthcare facilities to reduce hospital-acquired infections and limit the spread of resistant organisms. In addition, ICMR supports the

implementation of Antimicrobial Stewardship Programmes (AMSP) to ensure rational prescribing of antibiotics, optimize drug selection, dosage and duration of therapy, conduct prescription audits, and train healthcare professionals, thereby minimizing misuse and slowing the emergence and transmission of antimicrobial-resistant pathogens.

Ministry of Health and Family Welfare including Central Drugs Standard Control Organization (CDSCO) has taken various measures to monitor and regulate antibiotic prescriptions, especially for over-the-counter sales, to prevent misuse and address Anti-Microbial Resistance (AMR) issues:

(i) Antibiotics are included in Schedule H and H1 of the Drugs Rules, 1945. These drugs have specific caution labeling requirements and are required to be sold only under the prescription of a Registered Medical Practitioner.

(ii) The Drug & Cosmetics Rules, 1945 were amended with effect from 01.03.2014 incorporating a new Schedule H1 containing various antibiotics, Anti TB drugs and certain habit forming drugs. The supply of a drug specified in Schedule H1 is recorded in a separate register at the time of the supply and such records are required to be maintained for three years and are open for inspection.

(iii) Various Notices/ Advisories/ Letters have been issued to the State Drugs Regulators, and other stakeholders for strict compliance of the requirements and raising awareness in the public regarding adverse effects of misuse of antibiotics.

(iv) Sale of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, thereunder by the State Licensing Authorities (SLAs) appointed by State Government through a system of licensing and inspection. SLAs are legally empowered to take action against violation of provisions of the said Act and Rules.

(v) States have also been advised to ensure prescription of generic drugs and conduct regular prescription audits in public health facilities. Practice of prescription audit is one of the prerequisites for getting certified under the National Quality Assurance Standards (NQAS).

(vi) To promote judicious use of antibiotics and to create awareness about AMR, National Centre for Disease Control (NCDC) has developed media material including audios, videos, social media messages and Outdoor Media which are available in public domain and also shared with States/UTs for further dissemination.

(vii) The Ministry has also launched the Red Line Campaign to make people aware that medicines marked with a red vertical line on the packaging primarily antibiotics and other prescription drugs should not be taken without a doctor's prescription.

The labelling requirements for antimicrobials are provided under Rule 96 and 97 of Drug Rules, 1945. The Drugs Rules, 1945 have been amended in year 2023 by adding sub-rule (6) of Rule 96 to mandate that manufacturers of the top 300 drug formulation brands listed in Schedule H2 shall print or affix a Bar Code or QR Code on the primary packaging label, or on the secondary label where space is insufficient, to store data readable through software applications for authentication which also includes certain antimicrobials.
