

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

**LOK SABHA
UNSTARRED QUESTION NO. 5646
TO BE ANSWERED ON 27TH MARCH, 2026**

MISUSE AND OVERUSE OF ANTIBIOTIC MEDICINES

†5646. SHRI BRIJENDRA SINGH OLA:

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

- (a) whether the Government is aware that antibiotic medicines are being misused and overused in the country due to the absence of clear warnings or symbols on their packaging and, if so, the details thereof, State-wise;
- (b) whether the Government proposes to introduce special coding, colour coding, distinct markings, warnings or QR codes on the packaging of antibiotic medicines to enable patients and pharmacists to distinguish them from other medicines and if so, the details thereof;
- (c) whether the effectiveness of antibiotic medicines is decreasing due to their excessive or inappropriate use and, if so, the details thereof; and
- (d) whether Government has conducted any study to assess the adverse effects of the misuse of antibiotic medicines and, if so, the details thereof along with the efforts made to prevent such misuse?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE**

(SMT. ANUPRIYA PATEL)

(a) to (d): Antibiotics are covered under Schedule H & Schedule H1 of Drugs Rules, 1945 and are required to be sold by retail on prescription of Registered Medical Practitioner (RMP) only.

Regulatory control over the sale and distribution of drugs is exercised through a system of licensing and inspection by State Licensing Authorities (SLAs) appointed by State Government. In case of violation, SLAs are empowered to take action as per provisions of Drugs and Cosmetics Act, 1940 & Rules made there under.

As informed by Indian Council of Medical Research (ICMR), various studies carried out in India indicate widespread irrational use, including over-the-counter (OTC) sales without prescription, over prescribing by clinicians, self-medication and incomplete treatment courses by patients. However, ICMR has not undertaken any such study to determine whether the misuse is due to lack of clear warning symbols.

The labelling requirements for antimicrobials are provided under Rule 96 and 97 of Drug Rules, 1945. Further, 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.

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.

ICMR's report published annually is documenting increasing levels of resistance to commonly used antimicrobials in pathogens of public health importance. Typhoid causing organisms *S. typhi* are documenting 90% resistance to fluoroquinolones, ICMR annual report 2024-2025). Also increasing resistance to broad spectrum antimicrobials are being documented in pathogens like *E coli*, *Klebsiella pneumonia* and *Staphylococcus aureus*, which are also most commonly prescribed (Surveillance of Antimicrobial Consumption under National Antimicrobial Consumption Network (NAC-NET) data).
