

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

**LOK SABHA
UNSTARRED QUESTION NO. 4780
TO BE ANSWERED ON 28TH MARCH, 2025**

EXCESS USE OF OVER-THE COUNTER SALE OF ANTIBIOTICS

4780 ADV GOWAAL KAGADA PADAVI:

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

- (a) whether the Government has taken any steps to stop the excessive reliance on over-the-counter sale of antibiotics in the country and if so, the details thereof;
- (b) whether there is any strict law for enforcement in this regard and if so, the details thereof;
- (c) the measures taken/proposed to be taken by the Government to reduce the consumption of antibiotics by livestock animals which are eventually consumed by humans; and
- (d) the other steps taken/proposed to be taken by the Government to reduce the Anti-Microbial Resistance among humans?

**ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY
WELFARE
(SMT. ANUPRIYA PATEL)**

(a): Central Drugs Standard Control Organization (CDSCO) and Ministry have taken various regulatory 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 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 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). Rule 97 of Drugs and Cosmetics Rules, 1945 has been amended making it mandatory that the container of a medicine for treatment of food producing animals shall be labelled with the withdrawal period of the drug for the species on which it is intended to be used.
 - (v). The Department of Animal Husbandry, Dairying and Fisheries had issued a circular to all Directors/Commissioners (Animal Husbandry) of all state and UTs vide their letter no. 102-74/2014-Trade dated on 03.06.2014 and directed for judicious use of antibiotics for the treatment of ailing food producing animals and at the same time use of antibiotics in animal feed should also be stopped. Subsequently, Drugs Controller (India) had also issued an advisory to all States/UTs on 06.06.2014 that use of Antibiotics and Hormones in animal feed should also be stopped.
 - (vi). Colistin and its formulations have been prohibited w.e.f. 19.07.2019 to manufacture, sell and distribution for food producing animals, poultry, aqua farming and animal feed supplements.
 - (vii). Chloramphenicol and its formulations; and Nitrofurans and its formulations have been prohibited w.e.f. 12.03.2025 to import, manufacture, sale and distribution for use in any food producing animal rearing system.
- (b): Sale of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 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.
- (c): As informed by the Department of Animal Husbandry and Dairying (DAHD), following measures has been taken to reduce the consumption of antibiotics by livestock animals which are eventually consumed by humans:
- (i). The Department has developed the 'Standard Veterinary Treatment Guidelines (SVTGs) for Livestock and Poultry' which is a key reference document that outlines best practices in veterinary care to enhance livestock health and productivity while ensuring the responsible use of drugs including antimicrobials. Also, it provides a holistic approach to disease prevention through vaccines and biosecurity measures.
 - (ii). The Poultry Disease Action Plan has been formulated which emphasizes proactive disease management through biosecurity measures, enhanced surveillance, and vaccination protocols, thereby safeguarding both poultry population and public health.
 - (iii). The Department also promotes alternative to antimicrobials through the use of ayurvedic formulations and ethnoveterinary practices. The Bharat Pashudhan application under National Digital Livestock Mission provides management of

nearly 29 common ailments of dairy animals e.g. mastitis, indigestion, diarrhoea etc. using Ethno-Veterinary Medicine (EVM).

- (iv). The Department is implementing world's largest vaccination programme through the Livestock Health and Disease Control Programme for control of Foot and Mouth Disease (FMD), Brucellosis, Classical Swine Fever and Peste des Petits Ruminants (PPR). Also, under Assistance to States for Control of Animal Diseases (ASCAD), the department provides financial assistance to States for vaccination of livestock and poultry against economically important diseases.
 - (v). The department has constituted the Empowered Committee on Animal Health-Regulatory, a subcommittee to 'Assess and provide recommendations on submission of veterinary vaccines/biologicals/drugs for policy input'. The committee examines the proposals received from Drugs Controller (India) regarding import and manufacturing of drugs and vaccine including antibiotics keeping in view of the emergence of AMR.
 - (vi). The Department also issues advisories to the States/UTs for prudent use of the antimicrobials in livestock and poultry and provides technical inputs for banning of antimicrobials for use in livestock and also banning for use of growth promoters. Similarly, with the inputs of the department, Drugs Controller (India) has introduced the labelling of withdrawal period in the veterinary drugs which makes the livestock products safer for human consumption.
 - (vii). The department is also actively engaged in the formulation of the National Action Plan on Antimicrobial Resistance (NAP-AMR) - 2.0 for addressing the AMR challenges in the animal husbandry sector.
- (d): Various other steps taken by the Government to reduce the Anti-Microbial Resistance among humans are as under:
- (i). Standard Treatment Guidelines (STGs) have been issued by Ministry of Health and Family Welfare, Government of India and the same are available in public domain and can be accessed at <https://ncdc.mohfw.gov.in/guidelines-resources/>.
 - (ii). Government has issued Guidelines on Infection Prevention and Control which aim at prevention and control of healthcare associated infections to reduce the use of antibiotics in healthcare settings.
 - (iii). The Food Safety and Standards Authority of India (FSSAI) has issued a Notification prohibiting the use of 19 antibiotics and veterinary drugs at any stage of processing of meat, meat products, poultry and eggs, sea food or any variety of fish and fishery products and has specified tolerance limits for 103 antibiotics and veterinary drugs for various animal tissues and milk.
 - (iv). States have also been advised to ensure prescription of generic drugs and conduct regular prescription audits in public health facilities.

- (v). 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. Media materials are also available at <https://ncdc.mohfw.gov.in/iec-on-amr/>.
- (vii). Indian Council for Medical Research (ICMR) has undertaken several research initiatives including AMR network comprising 21 tertiary care hospitals. An Antimicrobial Stewardship (AMS) implementation project has also been initiated in these 21 hospitals, all of which have developed their own antibiotic policies. ICMR funds a total of 51 research projects spanning basic, clinical and applied research along with small and intermittent grants.
- (viii). ICMR released guidelines on Infection control in hospitals in 2016 to facilitate hospitals to develop infection control program which are available at https://www.icmr.nic.in/sites/default/files/guidelines/Hospital_Infection_control_guidelines.pdf.
