

F. No. AMR/Misc/02/NCDC-NAP-AMR/18

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India

Dated: 23/12/2019

Advisory

RATIONAL USE OF ANTIBIOTICS FOR LIMITING ANTIMICROBIAL RESISTANCE

Antimicrobial Resistance (AMR) is an increasingly serious threat to public health. The spread of multi-drug resistant bacteria and the lack of new antibiotics to treat infections caused by these organisms pose a rapidly increasing threat to human health which urgently needs to be tackled.

Ministry of Health and Family Welfare in consultation with various stakeholders developed National Action Plan on AMR (NAP-AMR), which was officially released on 19.04.2017. The NAP-AMR outlines the priorities and interventions planned which consider harmonized approach across various sectors to address the use of and resistance to antimicrobial agents in human health, agriculture, food products and the environment.

As a part of overall responsibility for ensuring the safety of public health and limiting development of antimicrobial resistance in the country, the CDSCO and Ministry of Health and Family Welfare have been continuously taking regulatory steps to curb and control indiscriminate use of antibiotics.

Details of regulatory steps taken in this regards are as under:

1. Antibiotics are included in Schedule H and H1 of the Drugs and Cosmetics Rules, 1945 and are required to be sold by retail only under the prescription of a Registered Medical Practitioner. A separate Schedule H1 under the Drugs and Cosmetics Rules, 1945 was introduced vide G.S.R 588 (E) dated 30.08.2013 containing antibiotics, Anti-TB drugs and certain habit forming drugs. The drugs falling under Schedule H1 are required to be sold in the country for stricter control over these drugs.
2. The Drugs and Cosmetics Rules, 1945 were amended vide G.S.R. 28 (E) dated 17.01.2012 for making it mandatory to mention withdrawal period on

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the label of veterinary drugs used in food producing animals to ensure that the food stuffs produced from the animals do not exceed the residual limit specified for them.

3. Colistin and its formulations have been prohibited on 19.07.2019 for manufacture, sell and distribution for food producing animals, poultry, aqua farming and animal feed supplements.
4. The Ministry of Agriculture also issued a circular to Directors/Commissioners of Animal Husbandry of all States and UT's requesting the State Govt. and Union Territories to advice State veterinarians, feed manufacturers and also the persons involved in the treatment of animals for judicious use of antibiotics and hormones for the treatment of ailing food producing animals.
5. Various Notices/Advisories/Letters have been issued to the State Drugs Regulators, and other stake holders for strict compliance of the requirements of Drugs and Cosmetics Act and Rules made thereunder and raising awareness in the public regarding adverse effects of misuse of antibiotics.

Steps required to be taken by stakeholders

1. **All State & UT Drugs Controllers** should sensitize their enforcement officials to keep strong vigil to ensure that such drugs are not sold by retail without prescription of Registered Medical Practitioners in accordance with Drugs and Cosmetics Act, 1940 and rules made thereunder.
2. **All India Organization of Chemists and Druggists** should play an active role to educate their members to follow the conditions of Licence for sale of drugs strictly and co-operate with regulatory authorities to prevent such sale of drugs.
3. The **Pharma Industry** should use their well-developed marketing network to discourage the pharmacists in selling of such drugs without prescription.

All the stakeholders are advised to join hands in rational use of antibiotics to adhere to the mission of use of medicines appropriately to safe guard right, safety and well- being of the patients.

(Dr. V. G. Somani)
Drugs Controller General (India)

Government of Karnataka
Drugs Control Department

No DCD/ADM/4/23-24

Drugs Control Department
Palace Road, Bengaluru
Dated: 16.11.2023

CIRCULAR

Sub: Status of Antimicrobial resistance (AMR) in Karnataka and way forward - Reg

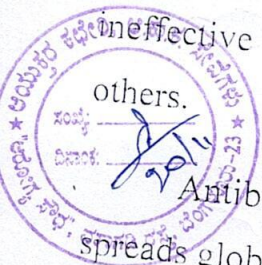
Ref: 1. Meeting held under the chairmanship of Honourable Health Minister on 9.11.2023 at Vikasa Soudha.

Antimicrobial Resistance (AMR) has been recognised as a serious and growing threat to public health. The emergence and spread of drug-resistant pathogens that have acquired new resistance mechanisms, leading to antimicrobial resistance, continues to threaten our ability to treat common infections.

The spread of multi-drug resistant bacteria and lack of new antibiotics to treat infections caused by these organisms pose a rapidly increasing threat to human health which urgently need to be tackled.

Antimicrobial resistance happens when microorganisms such as bacteria, fungi, viruses, and parasites change when they are exposed to antimicrobial drugs such as antibiotics, antifungals, antivirals, antimalarials, and anthelmintics. Microorganisms that develop antimicrobial resistance are sometimes referred to as "superbugs". As a result, the medicines become ineffective and infections persist in the body, increasing the risk of spread to others.

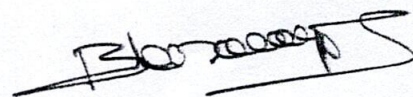
Antibiotics are becoming increasingly ineffective as drug-resistance spreads globally leading to more difficult to treat infections.



Antibiotics are included in Schedule H of the Drugs and Cosmetics rules 1945 and are required to be sold by retail only under the prescription of a Registered Medical Practitioner. Further in order to regulate the human consumption of antibiotics to restrict the over the counter availability of certain antibiotics, the Drugs Rules 1945 was amended incorporating a Schedule H1 under the Drugs Rules.

As a part of overall responsibility for ensuring the safety of public health and limiting development of antimicrobial resistance in the country, following regulatory steps to be taken to curb and control indiscriminate use of antibiotics.

1. Ensure strict compliance with the requirements of the Drugs and Cosmetics Act and Rules made thereunder to prevent retail sale of Antibiotics without prescription of RMP.
2. Raise awareness in the public about the adverse effects of misuse of antibiotics
3. Issue advisory to all chemists and Druggists Associations under your jurisdiction to play an active role to educate their members to follow the conditions of license for sale of drugs strictly and cooperate with regulatory authorities to prevent such sale of drugs.
4. All the enforcement officers of circle office are directed to verify the purchase, sale and stock of at least one Antimicrobial drug in every inspection carried by them and to record in the inspection report and take necessary action as per law.



Bhagoji T Khanapure
Drugs Controller

To:

1. All the Enforcement officers

Copy to,

1. The Principal Secretary Health and Family welfare department, Vikasa
soudha, Bengaluru for information
- ✓ 2. The Commissioner, Health and Family welfare department, Arogya
soudha, magadi road, Bengaluru for information
3. Additional Drugs Controller, Drugs Control Department for information

F.No. 12-01/23-DC (Pt-205)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi-110002, India

Dated: 02 FEB 2024

To,
All States / UTs Drugs Controllers

Subject: Information with respect to action taken to overcome antimicrobial resistance in your States - reg.

Sir,

The concern of Antimicrobial Resistance (AMR) has been highlighted as a global health priority in multiple high-level fora.

The primary goal of NAP-AMR (National Action Plan – Antimicrobial Resistance) is to protect the health of humans, animals, plants and environment by preventing emergence and transmission of AMR through effective sectoral and multisectoral evidence-based One Health approach.

Central Drugs Standard Control Organization (CDSCO) along with State Licensing Authorities is already involved in taking regulatory measures as per the NAP-AMR (National Action Plan-Antimicrobial resistance).

In view of the above, the matter was discussed in detail in 63rd DCC meeting held on dated 30.01.2024, with all the State Drugs Controllers and it was decided to have separate detailed discussion on the subject w.r.t enforcement activities in order to curb Antimicrobial resistance. Measurable and concrete action is required by all the Stakeholders to curb AMR.

Accordingly, it is proposed to hold the meeting with all States/ UTs Drugs Controllers under the Chairmanship of DCGI, on dated 14.02.2024. In this connection, you are requested to provide the following -

1. The existing mechanism to monitor the disposal of effluents from API & Formulation of antimicrobial manufacturing industries
2. The measures taken by your respective offices to prevent the sale of antibiotics without prescription.