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

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

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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

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.

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