

**Central Drugs Standard Control Organisation
Ministry of Health and Family Welfare**

ADVISORY

**RATIONAL USE OF ANTIBIOTICS FOR LIMITING ANTIMICROBIAL
RESISTANCE**

Date: 1st February, 2017

As a part of overall responsibility for ensuring the safety of public health and limiting development of antimicrobial resistance in the country, the CDSCO has been continuously taking steps to curb and control indiscriminate use of antibiotics. Such indiscriminate use may be due to easy availability of prescription drugs, injudicious use in hospitals as well as uncontrolled use in agriculture, animal husbandry and fisheries.

Steps taken by CDSCO in limiting antimicrobial resistance

1. A separate Schedule H1 under the Drugs and Cosmetics Rules, 1945 was introduced vide [G.S.R 588\(E\) dated 30.08.2013](#) containing carbapenem class and III & IV generation of antibiotics along with certain habit forming and Anti-TB drugs 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. 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 advise 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.
4. The Pharmacovigilance Programme of India (PvPI) has been entrusted with the responsibility of collecting, collating and analysing the adverse drug reactions of the medicines manufactured and marketed in India through its 203 Adverse Drug Reaction Monitoring Centres across the country. Besides this the PvPI has vast network of information collecting system with public and private participation to help the drug regulators to take appropriate measures on the matters related to the patient safety.

The PvPI through its 203 monitoring centres has been directed to carry out a surveillance programme at its centres in various hospitals to monitor the use of antibiotics, adverse reactions reported and cases of antibiotics resistance reported. They have also been asked to conduct awareness programme on monthly basis on misuse of antibiotics involving physicians, nurses, pharmacists, supply chain personnel as well as members of community.

5. [Indian Medical Association](#) through its President Dr. K.K. Agarwal has been requested to sensitize its members to follow Standard Treatment Guidelines while prescribing the antibiotics. He has also been requested to sensitize his members through his wide network of interactions through audio-visual programmes. He is also requested to take up the issue through other platforms of medical sciences.
6. [The Medical Council of India](#), Pharmacy Council of India, Nursing Council of India and Dental Council of India have also been requested to sensitize its registered members to be the part of this national issue on rational use of antibiotics.

Steps required to be taken by other stakeholders

1. **State Drugs Regulators** have been advised vide [Notice dated 16.01.2017](#) for strict compliance of the requirements of the Drugs and Cosmetics Act and Rules made and raising awareness in the public about the adverse effects of misuse of antibiotics.
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 optimal use of antibiotics to adhere to the mission of use of medicines appropriately to safeguard rights, safety and well being of the patients.

Yours faithfully,



(Dr. G. N. Singh)
Drugs Controller General (India)



(Dr. G. N. Singh)
DRUGS CONTROLLER GENERAL (INDIA)

Central Drugs Standard Control Organization
Directorate General of Health Services
Tele – 011-23236965
Fax - 011 -23236973
Email :- dcg@nic.in
Web : www.cdsc.org.in
FDA Bhawan, Kotla Road, New Delhi –110002.
Dated: 01.02.2017

To,

Dr. K. K. Agarwal
President, Indian Medical Association,
IMA House, Indraprastha Marg,
New Delhi- 110002

Sub: Rational use of antibiotics for limiting antimicrobial resistance- reg.

Sir,

Antibiotic resistance is the result of environmental and behavioral causes. Indiscriminate prescription of antibiotics and laxity in enforcement laws are the main causes of antimicrobial resistance. This may be due to injudicious use of antibiotics in hospitals as well as in private practice apart from easy availability of prescription drugs in the country.

In this regard it is requested that you may kindly sensitize your members to follow a Standard Treatment Guidelines while prescribing the antibiotics to the patients through your wide network of interactions with the members through the audio-visual programmes.

You may also take up the issue using other platforms of medical sciences to make this national issue of rational use of antibiotics a success.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

F. No. X-11026/64/2014-BD
Directorate of General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi
(O/o DCG (I))

Dated: 06/06/2014

To,

1. All State/UT Drugs Controllers

Sub: Use of antibiotics for treatment of food producing animals and in animal feed -regarding.

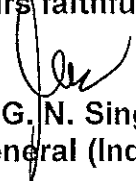
Sir,

The Drugs and Cosmetics Rules were amended by the Ministry of Health and Family Welfare vide Gazette notification G.S.R. 28(E) dated 17th January 2012, to make a provision 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. The Ministry of Agriculture, is a nodal Ministry for matters relating to livestock production, preservation, protection and improvement of stocks, dairy development etc. The Department of Animal Husbandry, Dairying and Fisheries under that Ministry has issued a circular to all Directors/ Commissioners (Animal Husbandry) of all State and UTs vide their letter no. 102-74/2014-Trade dated 3rd June, 2014 on use of antibiotics for treatment of food producing animals and in animal feeding. A copy of the letter is enclosed.

It has been stated in the letter that the State Governments and Union Territories are requested to advise the State Veterinarians, feed manufacturers and also the persons involved in treatment of animal for judicious use of antibiotics and hormones for the treatment of ailing food producing animals. An awareness programme at the consumer and farmers level may also be arranged. **At the same time use of antibiotics and hormones in animal feed should also be stopped.**

In view of the above you are requested to take up the matter with the Directors/ Commissioners (Animal Husbandry) in your State/ Union Territory for the compliance of the directions issued by the Department of Animal Husbandry, Dairying and Fisheries. Arrangements may also be made to give publicity to the contents of the directions issued so as to ensure compliance by the manufacturers involved in the production of such food stuffs from animals.

Yours faithfully,



(Dr. G. N. Singh)
Drugs Controller General (India)

1. Copy forwarded for information to
 - I. AS & DG, (CGHS), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi
 - II. JS (R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi

2. Copy forwarded for information and necessary follow up to
The Zonal /Subzonal offices of CDSCO.

No. 102-74/2014-Trade
Government of India
Ministry of Agriculture
Department of Animal Husbandry, Dairying and Fisheries

Krishi Bhawan, New Delhi,
Dated, 3rd June, 2014

To,
All Directors/Commissioners (Animal Husbandry)
Of all States and UTs.

Subject: Use of antibiotics for treatment of food producing animals and in animal feeding.

Sir,

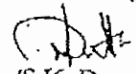
The primary use of antibiotics for animal treatment is as a schedule drugs for treatment of infectious and contagious diseases in animal. It is a well known fact that following administration of any drugs including antibiotics, there should be a withdrawal period to be given for food producing animals. In this regard, the Drug Controller General of India have issued a notification under the Drugs and Cosmetic Act, 1940 wherein the drug manufacturers has been directed that the container of a medicine for treatment of food producing animals shall be labelled with a specific withdrawal period of the drug for the species on which it is intended to be used. If the specific withdrawal period has not been validated, the withdrawal period shall not be less than seven days for eggs or milk, twenty eight days for meat from poultry and mammals including fat and offal, five hundred degree days for fish meat. The withdrawal period is the period of interval between the last administration of a veterinary medicine to animals under the normal conditions of use and production of food stuff from such animals so as to ensure that food stuffs do not contain residues in quantities in excess of the maximum permissible residue limits laid down.

2. Apart from above use, antibiotics are also used as feed premix for regular feeding in poultry and animals used for meat, milk and egg production. This kind of regular feeding of antibiotics has serious consequences on human being since residues of antibiotics may accumulate in meat, milk and eggs. Consumption of antibiotic contaminated meat, milk and eggs may develop antibiotic resistance in both human being and animals. This type of use of antibiotics should be discouraged and in this regard, the farmers/ industries and feed manufacturers should be advised/educated on not to use antibiotics for animal feeding.

3. Further, the use of hormones as growth promoters used in food producing animals should also be stopped since it has also adverse effect on human and animal life.

4. All the State Governments and Union Territories are requested to advice all the State Veterinarians, feed manufacturers and also the persons involved in treatment of animal for judicious use of antibiotics and hormones for the treatment of ailing food producing animals. An awareness programme at the consumer and farmers level may also be arranged. At the same time use of antibiotics and hormones in animal feed should also be stopped.

Yours sincerely,


(S.K. Dutta)

Asstt. Commissioner

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Copy to:

1. Drug Controller General of India, Directorate General of Health Services, FDA Bhawan, Kotla Road, New Delhi for further course of action in this regard.
2. Food Safety and Standard Authority of India, FDA Bhawan, Kotla Road, New Delhi to evolve system of estimating drug residue in domestic products:

F. No. 12-01/19-DC (Pt-09)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhavan, Kotla Road,
New Delhi

Dated: 15/02/19

NOTICE

Concerns have been raised from time to time regarding sale of medicines without prescription. Recently one representation has been received regarding sale of anti psychiatric medicines without any prescription. This office has sensitized all the concerned from time to time about the concerns of sale of drugs with prescription.

This office is again advising the supply chain system in India to follow strict requirements of Schedule H, H1 and X for sale of medicines, which are appended below

1. Schedule H: If it contains a substance specified in Schedule H be labelled with the symbol Rx and conspicuously displayed on the left top corner of the label and also be labelled with the following words-

'Schedule H drug-Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only'

2. Schedule H1: If it contains a substance specified in Schedule H1, the drug formulation shall be labelled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label, and also be labelled with the following words in a box with a red border-

"SCHEDULE H1 DRUG - WARNING:

- It is dangerous to take the preparation except in accordance with the medical advice.
- Not to be sold by retail without the prescription of a Registered Medical Practitioner."

3. Schedule X: If it contains a substance specified in Schedule X, be labelled with the symbol XRx which shall be in red and conspicuously displayed on the left top corner of the label and also be labelled with the following words-

'Schedule X drug-Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only'

The stakeholders are hereby advised for strict compliance of the requirement of the Drug and Cosmetics Act and Rules made thereunder by

- (i) Taking strong policy measures including stringent regulatory action on the over the counter (without prescription) sale of drugs included in the above Schedules.
- (ii) Raising awareness through Consumer Associations about the side effects of taking medicines without prescription for patient safety, their well being and protection of their health.



(Dr. S. Eswara Reddy)
Drugs Controller General (India)

To,

1. All State/UT Drugs Controllers
2. All Zonal/sub-zonal offices of CDSCO
3. Pharma/Consumer Associations



(Dr. G. N. Singh)
DRUGS CONTROLLER GENERAL (INDIA)

Central Drugs Standard Control Organization
Directorate General of Health Services
Tele – 011-23236965
Fax - 011 -23236973
Email :- dci@nic.in
Web : www.cdsc.nic.in
FDA Bhawan, Kotla Road, New Delhi –110002.
Dated: 01.02.2017

To,

1. **President, Medical Council of India**
2. **President, Pharmacy Council of India**
3. **President, Nursing Council of India**
4. **President, Dental Council of India**

Sub: Rational use of antibiotics for limiting antimicrobial resistance- reg.

Sir,

Antibiotic resistance is the result of environmental and behavioral causes. Indiscriminate prescription of antibiotics and laxity in enforcement laws are the main causes of antimicrobial resistance. This may be due to injudicious use of antibiotics in hospitals as well as in private practice apart from easy availability of prescription drugs in the country.

In this regard it is requested that you may kindly sensitize your members by raising awareness for rational use of antibiotics so as to curb antimicrobial resistance in the interest of patient safety.

You may also take up the issue using other platforms of medical sciences to make this national issue of rational use of antibiotics a success.

Yours faithfully,

(Dr. G. N. Singh)
Drugs Controller General (India)

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

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

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.

V/G

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