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Antimicrobial Resistance- CDSCO perspective

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CDSCO

Concern:



- Studies reveal that India has the biggest market for Antibiotics drugs and 50% of Antibiotics drugs are prescribed without any need.
- Available data indicates rising rates of AMR in the Country.

Developing NAP (National Action Plan)



The MOHFW identified AMR as one of the top 10 priorities for the ministry's collaborative work with WHO and aligned NAP with GAP

National Action Plan on Antimicrobial Resistance | India

1. Improve awareness and understanding of AMR through effective communication, education and training

2. Strengthen knowledge and evidence through surveillance

3. Reduce the incidence of infection through effective infection prevention and control

4. Optimize the use of antimicrobial agents in health, animals and food

5. Promote investments for AMR activities, research and innovations

6. Strengthen India's leadership on AMR

Drugs regulatory system in India

Drugs and Cosmetics Act and Rules

Objective:

To ensure safety, efficacy and quality of



Drugs

Biologicals

Medical Devices

Cosmetics

Veterinary Drugs.

7/13/2019

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- Drugs is in concurrent list of Indian Constitution
- It is governed by both Centre and State Governments under the Drugs & Cosmetics Act, 1940

Regulatory Agency Insights



Measures taken by CDSCO:

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 24 carbapenem and class III & IV generation of antibiotics along with certain habit forming and Anti-TB drugs for stricter control over these drugs.
2. Rule 97 [1(e)]- if it contains a drug substance specified in Schedule H1, be labelled with **symbol Rx**, which shall be in **red and conspicuously displayed on the left top corner of the label** and shall also be labelled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION

It is dangerous to take this preparation except in accordance with the medical advice.

Not to be sold by retail without the prescription of a Registered Medical Practitioner.

3. 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.

- **Unless otherwise validated, the withdrawal period shall not be less than**
 - **7days for Eggs or milk**
 - **28 days for meat**
 - **500 degree days for fish meal**

Regulatory Agency Insights cont....



4. CDSCO requested all the State Drugs Controllers to take up the matter with the State Veterinary Departments to ensure judicious use of antibiotics and hormones for the treatment of ailing food producing animals and not as growth promoter.
5. The Pharmacovigilance Programme of India (PvPI) through its more than 250 monitoring centers have been directed to carry out a surveillance programme at its centers 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 misuse of antibiotics involving physicians, nurses, pharmacists, supply chain personnel as well as members of community

Regulatory Agency Insights cont....



6. Indian Medical Association has been requested to sensitize its members to follow Standard Treatment Guidelines while prescribing the antibiotics.
7. MCI, PCI, 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.
8. State Drugs Controllers have been directed for strict compliance of the requirements of the Drugs and Cosmetics Act, 1940 and Rules, 1945 made there under
9. On 7.9.2018, 80 FDCs containing antibiotics were prohibited based on the recommendations of Expert Committee. Another approx. 25 such FDCs containing antibiotics have been recommended by the Committee as irrational.
10. Recently, the Central Govt. vide GSR 2607(E) dated 19.7.2019 prohibited Colistin and its formulations for food producing animals, poultry, aqua farming and animal feed supplements

Regulatory Agency Insights



- The supply of any drug supplied on the prescription of a Registered Medical Practitioner shall be effected only by or under the personal supervision of a registered Pharmacist.
- The supply of a drug specified in schedule H1 shall be recorded in a register at the time of supply giving the name and address of prescriber, name of patient, name of drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.
- The person dispensing a prescription containing a drug specified in [Schedule H and Schedule H1] [and Schedule X] shall comply with the following requirements in addition to other requirement of the rules:-
 - the prescription must not be dispensed more than once unless the prescriber has stated thereon that it may be dispensed more than once;
 - at the time of dispensing there must be noted on the prescription above the signature of the prescriber the name and address of the seller and the date on which the prescription is dispensed.

Non compliance attracts Penalty

Measures to be taken- Future steps



- State Drug Controllers will be sensitized in every Drugs Consultative Committee meeting for effective implementation
- All India Organization of Chemists and Druggists should play an active role to educate their members.
- The Pharma industry should use their marketing network to discourage selling of such drugs without prescription.
- The State Drugs Control Organizations should be strengthened
- Innovations shall be encouraged for developing new Antibiotics

Other measures



COMPREHENSIVE MULTISECTORAL APPROACH IS REQUIRED FOR RATIONAL USE OF DRUGS.

- Training to Doctors in Hospitals as well as Private practitioners for rational use of drugs as well as infectious diseases.
- Creating awareness in public for proper use of antibiotics.
- A celebrity campaign for AMR should be done
- Surveillance system has to be made more sound and logical.
- Improvement in sanitization.

THANK YOU