

CENTRE FOR SCIENCE AND ENVIRONMENT

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September 22, 2014

Dr G N Singh
Drugs Controller General (India)
Central Drugs Standard Control Organization
Government of India
FDA Bhavan, ITO, Kotla Road
New Delhi 110002

Subject: Regulating use of critically important antibiotics for humans in food-producing animals

Dear Dr G N Singh,

Antibiotic overuse and misuse in rearing food-producing animals including chicken and fish is strongly linked with greater emergence and spread of resistant bacteria thereby leading to growing problem of antibiotic resistance in humans. Antibiotics are considered as a precious resource for global public health and the need to preserve it has been strongly emphasised in policy and action of stakeholders across the world such as the World Health Organization (WHO) and several member countries of the European Union (EU). As a part of the required comprehensive approach, preserving antibiotics which are critically important for treating humans is considered as one of the most important measure to limit the impact of antibiotic resistance on public health.

In order to facilitate public health and animal health authorities in managing antimicrobial resistance, the WHO identified antibiotics which are critically important for human use in 2005. Its latest and third revision '**Critically Important Antimicrobials for Human Medicine**' was issued in 2011 (please see Annexure 1). The list based on set criteria, segregates several classes of antibiotics into 'critically important', 'highly important' and 'important'.

Critically important antibiotics can be characterised as either sole or one of the limited available treatment option to treat a serious human disease that may be caused by organisms transmitted via non-human sources or which may acquire resistant genes from them. Critically important antibiotic classes identified as per the latest WHO list are: aminoglycosides, carbapenams and other penams, 3rd and 4th generation cephalosporins, cyclic esters, fluoro- and other quinolones, glycopeptides, glycylicyclines, lipopeptides, macrolides and ketolides, monobactams, oxazolidinones, penicillins (natural, aminopenicillins and antipseudomonal), polymyxins, rifamycins and drugs used solely to treat tuberculosis or other mycobacterial diseases.

We, at Centre for Science and Environment understand that the Central Drugs Standard Control Organisation (CDSCO) has uploaded a 'Draft list of Veterinary approved drugs' on its website on Sept. 19, 2014. We have reviewed this list with reference to the WHO list of critically important antimicrobials (mentioned above). **We realise that there are several approved drugs and finished formulations for veterinary use which comprise antibiotics that belong to the critically important antimicrobial classes.**

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We also understand through our study on 'Antibiotics in chicken meat' and subsequent research that several such critically important antibiotics for humans are rampantly used in rearing poultry for meat but are not approved as per the CDSCO list of approved veterinary drugs. Kindly note that findings of the CSE study are shared with your office earlier.

We are writing to request you to take necessary steps to regulate use of these critically important antibiotics in food-producing animals. We urge the CDSCO:

- To remove antibiotics which belong to the critically important antimicrobial classes as per the WHO from the draft list of veterinary approved drugs. Approval of such antibiotics and their finished formulations should be withdrawn at the earliest. Accordingly, no approval should be granted in future. **Please see Annexure 2**
- To deny approval and take necessary action for veterinary use of critically important antibiotics that are commonly used in poultry as found by the CSE study but are not approved by the CDSCO as per the list for approved veterinary drugs. **Please see Annexure 3.**

Please let us know if you need any clarifications. We would be happy to discuss this with you.

We hope that you consider this important and urgent for action on this huge public health threat.

With best regards,

Yours cordially,

Chandra Bhushan

Copy to:

Dr. A Ramkishnan, Head of Veterinary Cell, Central Drugs Standard Control Organization