

Centre for Science and Environment recommendations: Modifications in Drugs and Cosmetics Act (1940) and Rules (1945)

SPECIFIC PROVISIONS AND THE RATIONALE FOR BETTER REGULATION OF ANTIBIOTIC USE IN ANIMALS

With the inclusion of below mentioned provisions we can up to a considerable extent regulate the antibiotic use in animals. The new provisions that should either be inserted or be deleted are as follows:

A. Definitions:

The Drug and Cosmetic Act is silent about definition of animals, food-producing animals, growth promotion, antibiotic growth promoter, mass disease prevention, therapeutic use, non-therapeutic use etc. These terms play a vital role to understand the entire issue around use of antibiotics in animals. The following definitions should be inserted in Section 3 of the Act in their respective alphabetic order.

Animal:-

Animal means any living member of the animal kingdom except human being.

Food producing animal:-

Food-producing animal means any animal that is fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption, but that belong to a species that is normally used for human consumption in the Community.

Growth promotion:-

Growth promotion in the context of food-producing animals refers to increase in productivity such as weight gain for increase of meat, increase of milk and egg production by other than purely nutritional means.

Antibiotic growth promoter:-

Antibiotic growth promoter refers to use of antibiotic to promote growth. Antibiotic in this case is mixed with feed as additive and is usually administered at sub-therapeutic levels for almost the entire life-cycle.

Mass disease prevention:-

Mass disease prevention in the context of food-producing animals refers to sub-therapeutic antibiotic administration to most or all animals in the absence of any disease or clinical sign of it. It is usually done through water for a limited number of days.

Therapeutic use:-

Therapeutic use of antibiotics in the context of animals refers to antibiotic administration at therapeutic level to treat the sick. Such drug use involves treatment for few days in select animals usually done through water, injections, drops etc.

Non-therapeutic use:-

Non-therapeutic use in relation to food-producing animals as part of intensive farm practices, use of antibiotics other than any therapeutic reasons, such as for growth promotion or mass disease prevention, this involves sub-therapeutic administration of antibiotics which is known to facilitate emergence of antibiotic resistance.

B. Regulated antibiotic use:

To regulate the use of antibiotic in food-producing animals, a provision has to be added in the Act. As per the provision, use of any antibiotic in food-producing animals shall be restricted with certain exceptions as such:

- a) In case of any necessity, antibiotic could be used only for therapeutic purposes. The authority will notify a list of antibiotic which could be used only for therapeutic purposes and shall be administered only after a prescription of a registered veterinarian.
- b) In case of use of antibiotic that is not notified, the authority must approve for the same and give reason thereof for such approval.
- c) The use of critically important antibiotics only be allowed in an exceptional scenario, such as outbreak, a national crisis situation or any like event

The provision should be added as Rule 68C in the Drug and Cosmetic Rules, 1945.

Prohibition, restriction in respect of use of antibiotics in animals- Use or application of any antibiotic in animals, internal or external for the purpose of diagnosis, treatment, mitigation or prevention of any disease or disorder is restricted.

Provided that where there is necessary to use or apply antibiotic in food-producing animals, use or application of such drug is restricted for therapeutic purpose only;

For the purpose of this proviso non-therapeutic purposes could be as such:

- a) Use or application of antibiotic for mass disease prevention i.e. treating all animals without any necessity;
- b) Use or application of antibiotic as growth promoter such as feed additives or any other such use;
- c) Any other use or application of antibiotic as deem proper and notified by concerned authority under the Act, time to time.

Provided further that where it is necessary to use or apply antibiotic in food-producing animals, special care has to be taken, and it has to be ensured that no antibiotics are ever used that are critically important for human beings, and could only be used as last resort at the event of any exceptional circumstances, such as outbreak duly after the approval of the authority.

For the purpose of this proviso antibiotic critically important for human being shall mean, as notified by the concerned authority taking into account the latest list notified by WHO ([Critically Important Antimicrobials for Human Medicine, 3rd Revision, 2011](#)).

Explanation: In the context of the provision, last resort shall construe the meaning last option for the purpose of diagnosis, treatment, mitigation or prevention of any disease or disorder:

- i) Which is exceptional in nature and rare event, such as outbreak, national crisis situation etc;
- ii) Which is accordingly approved by the authority.

C. All antibiotics as part of Schedule H1:

All antibiotics has to be in the Schedule H1 to ensure more stringent regulation. There are many antibiotics still left in the Schedule H or out of the schedule, whereby supply and sale of those antibiotics is relaxed in comparison to Schedule H1 standards. This would further enable recording of all antibiotic use including those for animals. It would help feed into the proposed national drug database system.

D. Indian Veterinary Pharmacopeia:

In spite of referring to the British Pharmacopeia for veterinary, the authority must adopt its own Pharmacopeia for veterinary i.e. an Indian version of Pharmacopeia for veterinary. The Act at several place, for drugs intended for veterinary use, the standards of strength, quality, purity, test etc. directs to those specified in the current edition of the British Pharmacopoeia Veterinary. In such case, it is important to have our own Pharmacopeia for veterinary.

E. Approved drugs for veterinary use:

The authority should develop and periodically update a list of veterinary approved drugs and thereafter the manufacture, sale and distribution of any listed drugs as per norms. The Government must put in place a procedure for approving drugs for veterinary use and such drugs shall be administered only after prescription of a registered veterinarian.

Provision relating to Veterinary Approved Drugs and their supply or sale has to be added after Rule 124A and the list of approved drugs for veterinary use should be added as Schedule Z of the Drug and Cosmetic Rules, 1945.

Procedure to be observed in respect of supply or sale of veterinary approved drugs-The supply or sale of any drugs has to be done in accordance with the list of approved drugs for veterinary use only with prescription of veterinarian registered by veterinary council of India. The supply or sale of any antibiotic listed as veterinary approved drugs has to follow the strict procedure laid down in Schedule H1, even if such antibiotic is not included in Schedule H1.

F. Extended Producer Responsibility (EPR) for expired/unused/discarded drugs:

Suitable disposal of expired, unused, discarded bulk drugs/formulations is important to regulate misuse of drugs and minimise damage on environment and human health. To limit emergence and spread of antibiotic resistance, suitable disposal of antibiotics is paramount as it would prevent illegal entry into food-producing animal industry and entire food chain through environment.

Under the Indian Pharmacopeia Commission, the National Formulary of India, a guidance document primarily for doctors, pharmacists and drug stores recognizes the importance of appropriate disposal of unused/expired pharmaceutical products. The Act on the other hand is silent regarding disposal of expired drugs, its recovery from users and liability of manufacturer/producer of drugs.

Considering the importance of regulating antibiotics, just as it has been done in case of e-Waste (Management and Handling Rules), 2011, the Act needs to introduce a provision for EPR. EPR in this case should entrust the responsibility on producer/manufacturer/importer of managing the disposal of drug after its end of life. The producer/manufacturer/importer should arrange for a system to collect expired drugs from bulk users such as hospitals, nursing homes, distributors and drug stores as well as drugs from individual households. It should also individually or collectively arrange for suitable disposal of such drugs. The producer/manufacturer/importer under the supervision/approval from the Authority, develop and run public information programs through mass media to educate and create awareness on safe disposal of antibiotics and collection centres/system arranged.

EPR for unused/old medicines is in place in Canada and some European countries like Austria, Belgium and France. The existing regulation in India does not take care

of the scenario in totality. The Bio-Medical Waste (Management and Handling) Rules, 1998 put the onus of disposing discarded and cytotoxic drugs on healthcare establishments such as hospitals, nursing homes, veterinary clinics. The Hazardous waste (Management, Handling & Transboundary Movement) Rules, 2008 do not address recovery of expired drugs.

In view of the above we must have specific provisions regarding collection, recovery, disposal of expired, unused, discarded drugs under the EPR for pharmaceutical industry. Therefore a provision in this regard should be inserted as Section 18C.

Provisions concerning extended producer responsibility- the manufacturer, producer, distributor or the importer of any drug, especially antibiotics, shall arrange drug take back programme as part of Extended Producer Responsibility after the end of life of drugs, from bulk users such as hospitals, nursing homes, distributors or drug stores; and from individual households; and under the supervision of the designated authority arrange and ensure safe disposal of such drug either individually or collectively.

In addition to these the manufacturer, producer, distributor or importer under the supervision and with due approval shall develop and run awareness programme for general public, regarding safe disposal of expired/unused drugs, especially antibiotics.

G. Penalty for offences for drug imports:

Penalty prescribed in Section 13 (offences regarding import of drugs and cosmetics) has to be increased in line with Section 27 (penalty for manufacture, sale, etc., of drugs in contravention of chapter IV of the Act) of the Act.

For the words *'three years and a fine which may extend to five thousand rupees'*, the words *'not be less than three years but which may extend to five years and with fine which shall not be less than one lakh rupees or three times the value of the drugs, whichever is more'* shall be substituted.

For the words *'extend to six months, or with fine which may extend to five hundred rupees'* the words *'not be less than one year but which may extend to three years and with fine which shall not be less than one lakh rupees or three times the value of the drugs, whichever is more'* shall be substituted.

For the words *'extent to three years, or with fine which may extent to five thousand rupees, or with both'* the words *'not be less than three year but which may extend to seven years or with fine which may extent to one lakh rupees or three times the value of the drugs, whichever is more, or with both'* shall be substituted.

H. Limit exemptions related to import of substances for non medicinal use:

The extent and conditions of exemptions from Chapter III of the Act as per Schedule D must not exempt possible non medicinal use of any drug, especially antibiotic to be used as animal feed additives/supplement or antibiotic as growth promoter for food producing animals. Therefore a provision restricting the use of any drug as feed additives/supplement or as growth promoter should be inserted in the chapter III of the Act as Section 9E, as well as in the Schedule D of the Rules as an exception.

Provision in the Chapter III of the Act could be as follows:

Exception regarding non medicinal use of drug- The extent and conditions of exemptions available under Schedule D shall not however exempt any possible use of antibiotic as animal feed additives or use of antibiotic as growth promoter, and shall not be allowed as non medicinal use.

Exception in the Schedule D as such:

Provided that antibiotic as animal feed additives/supplement or use of antibiotic as growth promoter for food-producing animals shall not fall under the exceptions of the Schedule.

I. Limit exemptions related to manufacture, sale and distribution of substances for non medicinal use:

The extent and conditions of exemptions from Chapter IV of the Act as per Schedule K must not exempt possible non medicinal use of any drug to be used as feed additives/supplement or as growth promoter. Therefore a provision restricting the use of any drug as feed additives/supplement or as growth promoter should be inserted in the chapter IV of the Act as Section 18C, as well as in the Schedule K as an exception.

The provision in the Chapter IV of the Act as follows:

Exception regarding non medicinal use of drug- The extent and conditions of exemptions available under Schedule K shall not however exempt any possible use of any drug or antibiotic as animal feed additives or use of any drug or antibiotic as growth promoter, and shall not be allowed as non medicinal use.

Exception in the Schedule K as such:

Provided that any drug or antibiotic as animal feed additives/supplement or use of any drug or antibiotic as growth promoter for food-producing animals shall not fall under the exceptions of the Schedule.

J. Labelling of drugs imported:

The importance of labelling of bulk drugs in regulating import is very important and any exception in this regard could otherwise allow or leave enough room for spurious, unbranded, unlabelled and unpacked, freely available antibiotics in the open market.

In respect of Rule 96 (viii), the item 9 of the Schedule C(1), i.e. *Antibiotics and preparations thereof not in a form to be administered parentally* needs to be labelled, because any possible contradiction regarding use of unlabelled, untraceable availability of antibiotic will be a threat again. As per item 9 of the Schedule C(1) drugs in bulk form which are not ready for use and not included in Schedule P must also bear on the label the date of expiry of potency fixed by the manufacturer. In this regard therefore delete the proviso Rule 96(viii).

Delete proviso to rule 96(viii):

Provided that drugs in bulk form included in Schedule C(I) which are not ready for use and not included in Schedule P need not bear on the label the date of expiry of potency fixed by the manufacturer.

In respect of Rule 96(xi), In addition to the other particulars which are required to be printed or written under these Rules, the label of innermost container of the drugs specified under Rule 96(xi) and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which should not be less than 1mm in width and without disturbing the other conditions printed on the label. However as per proviso (a) to the Rule 96(xi) the above mentioned condition shall not apply to preparations intended for animal treatment. In this context the exception clause (a) to the Rule 96(xi) should be deleted.

Delete proviso (a) to the Rule 96(xi):

Preparations intended for animal treatment.

K. National level Antibiotic Database:

A National level Database system has to be developed to keep track of antibiotic manufacture/production, distribution, sale and handling of expired antibiotics for ensuring unrestricted sale/availability of antibiotics in the market.

It could be made obligatory through a condition of licensing process to feed data by the manufacturer, producer, distributor, and seller in an interval of certain period as specified by the concerned authority. This must further be clubbed with the proposed EPR programme.

The following provision in this regard should be added as 65B of the Drug and Cosmetic Rule 1945.

National antibiotic data entry:-

All manufactures, sellers, distributors or importers shall be under obligation for approval of license, shall maintain proper recording of data regarding all use of antibiotics at all points to maintain a National Antibiotic Database.

SPECIFIC AREAS THAT NEED TO BE ADDRESSED FOR BETTER REGULATION OF HEAVY METALS IN COSMETICS

The issue of toxic heavy metal contamination through cosmetics needs to be addressed. CSE has also found presence of toxic heavy metals in commonly available Indian, International and herbal brands of cosmetics. While presence of mercury is unlawful and there are no set limits of Chromium and Nickel as per law in finished products. With younger generation beginning to use high amounts of cosmetics, the long-term cumulative impact of heavy metals on human health is likely to be more than ever before.

After assessing the existing regulations on cosmetics in the Drugs and Cosmetics Act and Rules and Bureau of Indian Standards, we believe that there is a need for reforms on how cosmetics are regulated and the way these regulations are implemented. In this regard, specifically, we bring to the attention the following points for consideration of the committee while finalising necessary modifications in the Drugs and Cosmetics Act and Rules. Specific provisions regarding these should be added at respective places.

A. Need finished product standards for toxic heavy metals: There should be standards for all toxic heavy metals individually in finished cosmetics products. Setting finished product limits for individual heavy metals would also address the issue of maximum limit for trace presence if at all it is allowed for a particular heavy metal. Importantly, there should be standards for all types of cosmetics, specifically those with physiological action such as fairness creams and herbal preparations.

A provision to address this issue should be placed in Rule 150A: Standards for Cosmetics and Schedule S

B. Independent assessment system to approve products: A robust system should be in place to ensure that products are approved before they enter into market. The current system depends only on the information provided by the companies and has no independent assessment before approving the product.

A provision to address this issue should be placed in Rule 142: conditions for licence

C. A public disclosure and warning system: A system needs to be in place that makes the consumer aware about the types and levels of heavy metals present in all cosmetic products. It could be on the lines of a database that is open to public. The health impact of heavy metals along with advisory notes could also be a part of such information. There should also be a 'safety alert' system that timely warns the consumer about potential hazardous presence of heavy metals in a particular brand/batch. Such message could be broadcasted in mass media to prevent further usage of such products/batch.

A provision to address this issue should be added in Chapter III: Import of Drugs and Cosmetics and Chapter IV: Manufacture, Sale and Distribution of Drugs and Cosmetics