# REGULATIONS AND POLICIES ON THE USE OF ANTIBIOTICS IN FOOD ANIMALS IN THE PHILIPPINES

**DAVINIO P. CATBAGAN, DVM**
**Assistant Secretary for Livestock**
**Department of Agriculture**

# ANTIBIOTICS

- Any of a large variety of chemical compounds and physical agents that are used to destroy microorganisms or to prevent their development

- Include synthetic chemicals as well as chemical substance or metabolic products made by microorganisms and chemical substance derived from plants.

# THE LEGAL BASES FOR THE REGULATION ON THE USE OF ANTIBIOTICS:

## A. Republic Acts (RAs)

1. R.A. 9711 : Food and Drug Administration Act of 2009
2. R.A. 8203 : An Act Prohibiting Counterfeit Drugs, Providing Penalties for Violations and Appropriating Funds Therefore

3. R.A. 6675 : Generics Act of 1988

4. R.A. 3720 : Foods, Drugs and Devices and Cosmetics Act

5. R.A. 1071 : An Act to Regulate the Sale of Veterinary Biologics and Medicinal Preparations

# THE LEGAL BASES FOR THE REGULATION ON THE USE OF ANTIBIOTICS:

## B. ADMINISTRATIVE ORDERS

1. Joint DOH and DA Administrative Order No. 2013-0026: Rules on the Regulation of Veterinary Drugs and Products, Veterinary Biological Products, and Veterinary Drug Establishments
2. DA AO 33 DOH AO III-A Series of 1991: Rules and Regulations on Registration of Veterinary Drugs and Products
3. DA AO 39 DOH AO III-B Series of 1991: Rules and Regulations to Implement Prescribing Requirements for the Veterinary Drugs and Products

4. DA AO 138 DOH AO 100 Series of 1990: Regulations for the Licensing of Veterinary Drug and Product Establishments and Outlets
5. DA AO 40 DOH AO III-C Series of 1990: Rules and Regulations on Dispensing of Veterinary Drugs and Products
6. DA AO 40 DOH AO III-L Series of 1990: Guidelines on Advertisement and Promotions of Veterinary Drugs and Products

# IMPLEMENTING AGENCIES IN THE REGULATION OF VETERINARY DRUGS AND PRODUCTS (VDAP)

- By virtue of the existing laws, the Food and Drug Administration (FDA) of the Department of Health (DOH) is mandated to regulate veterinary drugs and products.

- The Bureau of Animal Industry (BAI) by virtue of the delegated authority given by FDA through the Joint DOH – DA Administrative Orders assists in the regulation of veterinary drugs and products.

# Registration of Products and Establishments with FDA/BAI

All veterinary drugs and products including antimicrobials are required to be registered before these are imported, manufactured, distributed, marketed and used.

Likewise any person desiring to operate or establish a veterinary drug and product establishment shall first secure a license to operate.

# DELINEATION ON PRODUCT CATEGORIES AND DOSAGE OF VETERINARY PRODUCTS REGULATED BY FDA AND BAI

| The **FDA** shall regulate the registration of the following veterinary drug and products: | The **BAI** shall regulate the registration of the following veterinary drug and products: |
|---|---|
| A. Finished pharmaceutical dosage forms such as but not limited to:<br><br>1. Oral dosage forms such as capsules, tablets, bolus, paste, powder for suspension, granules for suspension, powder, solution, syrups, emulsions<br><br>2. Injectables such as; solutions, suspensions, powder for injections, granules for injections, parenterals | A.1 Pre-mixes, soluble powder and other preparations (but not limited to solution, suspension, granules, powder, emulsions) added to feeds or water, feed supplements, feed additives and other drinking / dipping solutions intended for mass administration for terrestrial and aquatic animals<br><br>2. Veterinary vaccines, diagnostic kits and reagents, veterinary medical devices and other biological products |

# DELINEATION ON PRODUCT CATEGORIES AND DOSAGE OF VETERINARY PRODUCTS REGULATED BY FDA AND BAI

| | |
|---|---|
| 3. External preparations such as: topical suspension, creams, ointments, lotions, aerosols, spray, pastes, gels, powders, medicated soaps and shampoo, solutions, medicated collars<br><br>4. Ophthalmic or otic creams, ointments, solutions or suspensions | 3. Non-medicated soap and shampoo, toothpaste, colognes, conditioners, talc/dusting powder, coat shine oil, breath freshener, plaque remover, mouth wash, coat deodorants, bedding and other grooming products<br><br>4. Dips for animals and eggs<br><br>5. Disinfectants that are intended for veterinary and aquaculture use including their environment or surroundings, facilities and equipment |

# DELINEATION ON PRODUCT CATEGORIES AND DOSAGE OF VETERINARY PRODUCTS REGULATED BY FDA AND BAI

| | |
|---|---|
| B. Active pharmaceutical ingredients and excipient intended for use as a component in the manufacture of the products mentioned in A. | 6. Probiotics that are intended for animal facilities and/or environment including pond or pond water or deodorizer, absorbent, disinfectant, sanitizer, etc.<br><br>B. Active pharmaceutical ingredients and other raw materials intended for use as a component in the manufacture of the products mentioned in A1-6 exclusively intended for veterinary use. |

| FDA shall: | BAI shall: |
| --- | --- |
| ○ regulate the licensing of manufacturers, traders, and/or distributors (importers, exporters, wholesalers) of the products classified in A and B<br>○ monitor veterinary drug and product establishments identified in A and B excluding <u>outlets</u><br>○ issue import permit for raw materials and/or API and raw materials for products classified in A and B | ○ regulate the veterinary drug manufacturers, traders, importers, distributors, exporters, wholesalers and outlets of the products<br>○ monitor the products and establishments under its jurisdiction<br>○ issue import permit for products mentioned above. |

# Requirements for labeling

All registered veterinary drugs and products particularly the antibiotics must be properly labeled and must contain the following information:

- name of the product (generic name alone or with brand name as the case may be)
- dosage form and strength
- pharmacologic category
- Rx symbol in case of prescription drugs
- Name and complete address of manufacturer, and when applicable, the name of the trader

# Requirements for labeling

- Registration number
- For veterinary use only
- Net content
- Formulation
- Indication/s
- Contraindication
- Precaution
- Warning
- Withdrawal period

# Requirements for labeling

- Antidote
- Mode of administration/direction for use
- Batch and lot number
- Date of manufacture and expiry date
- Storage condition
- For prescription product- Foods, Drugs and Devices and Cosmetics Act prohibit dispensing without prescription by a duly licensed veterinarian

# Requirements for Advertising or Promotion of VDAP

- No person shall advertise or promote VDAP unless such products are duly registered with FDA or BAI

- All therapeutic claims for VDAP in advertising or promotion materials must be based on adequate scientific, pharmacological, technical and clinical evidence, responsible veterinary medical opinion or long experience demonstrating their safety, efficacy and therapeutic indication approved by FDA or BAI

# WORLD ORGANIZATION FOR ANIMAL HEALTH (OIE)

- Provides guidance on the responsible and prudent use of antimicrobials in Veterinary Medicine with the aim of protecting both animal and human health as well as the environment
- Recommend the implementation of the responsible and prudent use of antimicrobial agents to improve animal health and animal welfare while preventing the emergence and spread of **antimicrobial-resistant** bacteria in animal and humans

The BAI adopts for implementation the OIE guidance on the responsible and prudent use of antimicrobial agents to ensure the rational use of these products.

**RATIONAL USE OF VETERINARY DRUG PARTICULARLY ANTIBIOTICS is based on the Rule of Right:**

- ✓ Right drug
- ✓ Given to the right patient
- ✓ At the right time
- ✓ With the right dosage
- ✓ And the right route of administration


# *Thank you!*