

August 30, 1991

DEPARTMENT OF AGRICULTURE

Administrative Order No. 40
Series 1990

DEPARTMENT OF HEALTH

Administrative Order No. 111-C
Series 1990

**SUBJECT: RULES AND REGULATIONS ON DISPENSING OF VETERINARY
DRUGS AND
PRODUCTS**

Pursuant to R.A. No. 3720, as amended by Executive Order No. 175 otherwise known as the "Foods, Drugs and Devices and Cosmetics", R.A. No. 6675, otherwise known as the "Generics Act of 1988", R.A. 382 known as the "Veterinary Practice Act", R.A. 5921 known as the "Pharmacy Act", R.A. 6425 known as the "Dangerous Drugs Act 1972", as amended R.A. 1556, otherwise known as the "Livestock and Poultry Feeds Act", R.A. 1071, an Act to regulate the sale of veterinary biologics and medicinal preparation and R.A. 3101, an Act authorizing the Director of the Bureau of Animal Industry, subject to the approval of the Secretary of Agriculture and Natural Resources to promulgate regulations for the preparation, sale, traffic in, shipment and importation of viruses, sera, toxins or analogous products used for the treatment of domestic animals, the following are hereby promulgated for the information guidance and compliance of all concerned:

Section 1. DEFINITION OF TERMS

- 1.1 "Dispensing" refers to the act by a duly-licensed pharmacist or veterinarians of filling a veterinary prescription or veterinary drug order.
- 1.2 "Generic Dispensing" refers to dispensing the client's'/buyer's choice from among generic equivalents.
- 1.3 "Partial Filling of Veterinary Prescription or Veterinary Drug Order (VDO)" refers to dispensing less than the total number of units prescribed.

- 1.4 “Veterinary Drug and Product Outlet” refers to drugstore, pharmacy or other business establishment registered with Bureau of Food and Drugs (BFAD) Bureau of Animal Industry (BAI) which dispenses or sells veterinary drugs and products.

Section 2. GUIDELINES ON DISPENSING BASED ON PRIOR LAWS

Prior to the Generics Act of 1988, the following general guidelines on dispensing have been operative. In order to have an integrated implementation of all relevant guidelines on dispensing these guidelines based on prior laws are restated hereunder.

2.1 “Veterinary Presentation or Ethical Drugs” refer to any drug preparation that is to be dispensed only upon written order of a duly-licensed veterinarian for the treatment of a condition or a diagnosed disease of animals.

2.2 Non-Prescription or Over-the-Counter (OTC) or Self-Service (SS) Veterinary Drugs” refer to drug preparations that can be approved for animal use and even without the written order of a duly-licensed veterinarian.

2.3 All prescriptions for veterinary prescription or ethical drugs in a drug outlet shall be kept in file for two (2) years and recorded in a prescription book duly-registered BFAD which shall open for inspection to Food and Drug Inspectors and Biological and Feed Product Inspectors at any time during business hours of the outlet. The prescription book shall be kept for two (2) years after the last entry.

Section 3. ADDITIONAL GUIDELINES ON DISPENSING TO IMPLEMENT THE GENERICS ACT OF 1988

In addition to the guidelines contained in Section 2, the following shall specifically guide dispensing under the Generics Act of 1988;

3.1 All veterinary drug and product outlets are required to practice generic dispensing as defined in Section 1.2 of these Rules and Regulations, with some exceptions, modifications or qualification in certain cases or circumstance, as described in Section 3.2 and 3.4

3.1.1 Veterinary Drug and Product Outlets as defined in Chapter II of Administrative Order No. __ Regulations for Licensing of Veterinary Drug and Product Establishments and Outlets.

In order to ensure the informed choice and use of veterinary drugs and products by the client/buyer, the veterinary drug and product outlets is required to:

3.1.1.1 Inform the client/buyer of all available veterinary drugs and products generically equivalent to the one prescribed with their corresponding prices.

3.1.1.2 For this purpose, all veterinary drug and product outlets shall post in a conspicuous place in their establishment a list of veterinary drugs and products using generic names with their brand names, if any, and their corresponding current prices. A handbook or directory containing the above required information, readily accessible to the client/buyer shall be considered substantial compliance.

3.2 Recognizing the special needs and circumstances of veterinary clinics, veterinary hospitals and farms, they shall be allowed to maintain veterinary drug and product storage area. A veterinary drug and product storage area refers to a place in the veterinary clinic, hospitals and farm where drugs and veterinary products are stored for use within the veterinary clinic, hospital and farm.

3.3 In dispensing veterinary drugs and products in unit dose or veterinary drugs and products which are not in their original containers but transferred to small bottles, tin cans, boxes plastic and/or paper envelopes and the like, the pharmacist/veterinarian shall place legibly on the required drug outlet's label the following information:

1. Name of the client;
2. name of patient, when applicable;
3. Species of client;
4. Generic name of the drug;
5. Brand name in parenthesis, if any;
6. Dosage strength;
7. Expiry date;
8. Direction for use; and
9. Name of pharmacist/veterinarian with their license number.

3.4 In partial filling of the prescription/veterinary drug order the following shall be written on the face of the prescription:

1. the date of partial filling
2. the quantity served and balance of the prescription unserved; and
3. name and address of the veterinary drug and product outlet

The partially filled prescription/veterinary drug order shall be returned to the buyer after recording the partial filling on the prescription book. The veterinary drug and product outlet which completes the filling of the prescription veterinary drug order shall keep the prescription in the file.

3.5 Dispensing Drugs in List A and List B

In dispensing drugs included in List A (Prohibited and Regulated Drugs) and List B (Drugs Requiring Strict Precautions in their Use), attached as Annex A and B respectively, the following shall be observed:

- 3.5.1 Dispensing must be done by the pharmacist/veterinarians who shall affix his/her signature on the prescription/veterinary drug order filled.
- 3.5.2 The order and instructions of the veterinarian as written on the prescription/veterinary drug order, must be precisely followed.
- 3.5.3 Partial filling of prescription/veterinary drug order for drugs belonging to List A shall not be allowed.

Section 4. VIOLATIONS ON THE PART OF DISPENSERS AND VETERINARY DRUG AND PRODUCT OUTLETS

The following acts of commissions are considered violations of these rules and regulations:

- 4.1 Imposing a particular brand or product on the buyer.
- 4.2 Inaccurate dispensing i.e. dispensing a veterinary drug and product which does not meet the prescription/veterinary drug order as to or all of the following: active ingredient, dosage form and strength.
- 4.3 Failure to post or make accessible the required up-to-date information on veterinary drugs and products.
- 4.4 Failure to adequately inform the buyer on available veterinary drugs and products that meet the veterinary prescription/veterinary drug order.
- 4.5 Failure to indicate generic name/official name designated by BFAD/BAI and other required information on the drug outlet's label of the dispensed veterinary drug and product.
- 4.6 Failure to record and keep prescriptions/veterinary drug orders filled.

4.7 Failure to report to the nearest DOH/DA office cases of violative erroneous, and/or impossible prescription/veterinary drug orders within three (3) months after receipt of such prescription/veterinary drug orders.

Section 5. REPORTING AND MONITORING OF NON-COMPLIANCE

Any interested party may report any verifiable violation of these Rules and Regulations to the nearest DOH/DA-BAI office. The local DOH/DA-BAI office is responsible for giving notice to erring pharmacist/veterinarian, drug outlets and for transmitting the report on violations to the Secretary of Health/Secretary of Agriculture or the fiscal's office for appropriate action.

Section 6. ADMINISTRATIVE SANCTIONS

For violation of these Rules and Regulations, the following sanctions, after due notice and summary hearing, may be imposed:

6.1 Suspension, or revocation of the license to operate the veterinary drug and product outlet by the Secretaries of Health / Agriculture.

6.2 Professionals directly involved in the violations shall be recommended by the Secretaries of Health / Agriculture for appropriate administrative sanctions by the Philippine Regulation Commission (PRC).

Section 7. CRIMINAL LIABILITY

The imposition of the above sanctions does not preclude the institution of appropriate criminal proceedings pursuant to Section 12 of RA 6675 known as the "Generics Act of 1988", R.A. 1556 known as the livestock and poultry feeds Act, R.A. 1071, R.A. 3101 and other relevant laws, upon receipt of complaints or reports of violations.

Section 8. TIMETABLE OF IMPLEMENTATION

In order to give all affected parties adequate time for learning and adjustment, the implementation of these Rules and Regulations shall be in three (3) phases, as follows:

Phase 1 Education Drive and Information Dissemination

This phase shall be from the date of the effectivity of these Rules and Regulations up to six months during this period, the DOH/DA-BAI in cooperation with the Department of Education Culture and Sports, the Department of Local-Government and the Philippine Information dissemination and education drive concerning the provisions of these Rules and Regulations as well as the Generics Act of 1988.

Phase 2 Monitoring of Compliance Without Sanctions of Penalties

Within six months the DOH/DA-BAI shall monitor voluntary compliance with the provisions of the Rules and Regulations on Prescribing and Dispensing. During this period, the associations of affected professionals are enjoined to promote compliance in order to achieve a smooth transition to the next phase of full implementation.

Phase 3 Full Implementation

Beginning August 1, 1991 the DOH/DA-BAI and the other relevant agencies of governments shall monitor compliance with these Rules and Regulations and all violations shall be subject to the appropriated sanctions and penalties provided for under these Rules and Regulations and all violations shall be subject to the appropriated sanctions and penalties provided for under these Rules and Regulations and the Generics Act of 1988.

Section 9. SEPARABILITY CLAUSE

In case any provision of this Administrative Order is declared contrary to law or unconstitutional, other provisions which are not affected thereby shall continue to be in force and in effect.

Section 10. REPEALING CLAUSE

All Administrative Orders, Rules and Regulations and other Administrative issuances or parts thereof, inconsistent with the provisions of the Administrative Order are hereby repealed and modified accordingly.

Section 11. EFFECTIVITY

This Order shall take effect fifteen (15) days after its publication in two (2) newspapers of general circulation.

(Sgd.) SENEN C. BACANI
Secretary of Agriculture

(Sgd.) ALFREDO R.A. BENGZON, M.D.
Secretary of Health

