

I
RECOMMENDED GUIDELINES FOR SUPERVISING
THE USE AND DISTRIBUTION OF VETERINARY
PRESCRIPTION DRUGS DISPENSED OR USED
BY VETERINARIANS IN PRIVATE PRACTICE

- 1) A veterinarian-client-patient relationship (VCPR) must exist. The term "veterinary prescription drug" includes drugs labeled for use by or on the order of a licensed veterinarian, and any other drugs used for purposes or dosages not described on the drugs' label. Prescription drugs should be dispensed only by or on the order of a veterinarian.
- 2) Lay staff should dispense such drugs only after receiving specific instructions from a veterinarian.
- 3) Each veterinary practice should maintain a listing of the livestock enterprises with which a valid VCPR exists.
- 4) Records should be maintained to show the prescription drugs that may be supplied to each client with whom a valid VCPR exists. Such records should indicate the veterinarian(s) who has the animals under his or her care. Permission to dispense prescription drugs should be based on records and histories of animals seen or treated on the owner's premises. This record of drugs that may be dispensed should not be changed without the permission of the responsible veterinarian, who should update each record on a quarterly basis.
- 5) There should be constant reinforcement of instructions to lay staff that veterinary prescription drugs are to be dispensed only on the order of a veterinarian, and only when a valid VCPR exists. Otherwise veterinary prescription drugs should not be dispensed. The drugs dispensed should be invoiced with the name and address of the client. Cash sales invoices that do not identify the client are not a proper record and leave no trail or record for follow-up.
- 6) Veterinary prescription drugs should be stored separately from other drugs on the practice premises. These drugs should be clearly distinguishable and separated from over-the-counter (OTC) drugs.
- 7) Veterinary prescription drugs should not be displayed on open counters that are readily available to the public.
- 8) All veterinary prescription drugs should be properly labeled when dispensed.
- 9) On the farm or ranch, veterinary prescription drugs should be kept in minimal quantities.
- 10) Concerted effort should be made to instruct the clients that veterinary prescription drugs should be stored securely on the farm or ranch, preferably under lock, with only a minimal number of personnel on the farm or ranch having access to those drugs. Effort should be made to persuade each client to keep a complete record of all animals

treated, which would include identification of animal(s), drug(s) used, amounts used, duration of treatment, and final disposition of the animal(s), i.e., date sold, returned to herd, or died.

11) Instructions for the use of each veterinary prescription drug should be written by the responsible veterinarian. These instructions should be posted in the area on the owner's premises where the drugs are kept. These instructions, the drug storage area, and the drugs themselves should, if possible, be examined at least quarterly with the client, to assure cleanliness, orderliness, purity, and nonexpired dating.

12) To the extent applicable, only legally available drugs should be used or dispensed for use.

13) For at least three years, the responsible veterinarian should keep records of all veterinary prescription drugs dispensed and used in the practice.

EPILOGUE

EPILOGUE TO THE RECOMMENDED GUIDELINES FOR SUPERVISING THE USE AND DISTRIBUTION OF VETERINARY PRESCRIPTION DRUGS DISPENSED OR USED BY VETERINARIANS IN PRIVATE PRACTICE

The purpose of this epilogue is to expound on the reasons for each guideline statement, to give definitions of terms used, and to incorporate into one document the many facets of a complex subject.

These guidelines contain the basic elements necessary to supervise drug usage and distribution with purpose and conviction. They also provide uniformity in the profession's approach to fulfilling that mission. Currently, no uniform set of procedures for supervising veterinary prescription drugs exist at the state, national, or local level. If the profession will adopt and support the concept of supervision of prescription drugs including those requiring extra-label use, precedence can be established. Given such precedence, the illegal can be more easily delineated from the legal. A violator is one not conforming to the established "state-of-the-art."

Until the profession establishes guidelines, it will remain difficult to attain judgements on the illegal use and distribution of the drugs.

Recommended Guidelines

The AVMA recommends that each state association and practice specialty organization use these guidelines as models, and work to incorporate them, with modifications deemed appropriate, into their constitution and bylaws as minimal standards of practice.

Veterinary Prescription Drugs

Veterinary prescription drug means a drug, because of toxicity or other potential for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a veterinarian. Therefore, it is required by federal law that such drugs be labeled with the statement: "Caution. Federal law restricts this drug to use by or on the order of a licensed veterinarian."¹ For purposes of these guidelines, the term veterinary prescription drug will also include those drugs used for purposes or dosages not stated on the label.

There is considerable confusion over what is and what is not a prescription veterinary drug. Such phrases and words as "For Veterinary Use Only", and "Sold to Veterinarians Only" are company policy statements and do not refer to the drug's prescription status.

Extra-label Use of Drugs

Extra-label use means the actual or intended use of a drug in animals in a manner that is not in accordance with the drug's labeling.²

In circumstances when no drug is legally available for the treatment of a specific disease in the species involved, or in circumstances when the dosage of a drug as specified in the labeling is ineffective, use of a drug in a manner not specified in the labeling may be considered except when such use is specifically prohibited in the intended species. A drug may be used in a manner not specified in the labeling only under the supervision of a veterinarian and only if a valid VCPR exists. Before a veterinarian may consider such use, a careful medical diagnosis must first be made within the context of a valid veterinarian-client-patient relationship. Following extra-label use of a drug, the veterinarian must give the producer specific written instructions and precautions pertaining to the withholding time of animals or animal products from marketing channels to ensure that animals and products are free of the drug's residues.³

Veterinarian-Client-Patient Relationship

The VCPR is a relationship wherein all of the following conditions have been met:

- 1) The veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the instructions of the veterinarian.
- 2) The veterinarian has sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.
- 3) The veterinarian is readily available for follow-up in case of adverse reactions or failure of the treatment regimen.^{4,5,6}

This definition of the VCPR, developed by AVMA, is broad in scope. It must cover many types of practices covering several species of animals.

Additionally, certain conditions make it economically irrational to require personal visits with every client and patient to establish a VCPR. The small backyard owner with five calves or pigs, the small rancher forty miles away, the backyard 4-H sheep, and the backyard milk cow place a severe economic burden on the practitioner and the owner. Some latitudes from the strict interpretation of the VCPR definition should be understandable under such conditions. Appropriate medical

consultation, filling the requirements for labeling and instructions, and the use of good judgment and common sense should be considered as proper conduct under such conditions.

Concept of a Veterinary Practice

Veterinary prescription drugs are to be dispensed by the licensed veterinarian within the course of professional practice. This means the veterinarian is licensed or otherwise properly authorized under state law to practice veterinary medicine in the state, and that a valid VCPR exists. Veterinarians who are employees of drug manufacturers or distributors and veterinarians who operate their own drug distributorships cannot legally sell veterinary prescription drugs or issue prescriptions or orders for them outside the scope of a professional veterinary practice.⁷

Lay Staff

Recommendations 2 through 7 are suggestions to decrease the possibility of inadvertent illegal dispensing by clinic personnel and to aid the staff in carrying out the instructions of the responsible veterinarian. At least one state has pharmacy laws that require the dispensing veterinarian to personally supervise the filling of a drug order involving prescription drugs.⁹ The Model Veterinary Drug Code presently being prepared by the Association of Food and Drug Officials addresses this issue. It is important that the responsible veterinarian be permitted to supervise the dispensing of veterinary prescription drugs by a regular employee who, in the judgment of the veterinarian, is a competent individual. That person or persons would be acting under the supervision and control of the veterinarian who is available when needed, even though not physically present at the time.

In hospitals or clinics with a large staff, it may be prudent in some cases to designate two or three key people as "keepers of the drugs." These key people would be the ones given authority to dispense veterinary prescription drugs on the veterinarian's directions.

Because of confusion about what a prescription drug is, segregation of the veterinary prescription drugs from over-the-counter drugs would be helpful to the lay personnel. It also would be helpful to clearly distinguish veterinary prescription drugs, by some identifying mark (such as a large red dot sticker).

It is AVMA policy, adopted in 1984, that direct-to-owner advertising or displaying of veterinary prescription drugs be discouraged. Additionally, the human medical field and some consumer groups oppose direct-to-consumer prescription drug advertising. For these reasons, it is recommended that veterinary prescription drugs not be displayed on open counters, readily available to the public.

Labels

All veterinary prescription drugs should be properly labeled when dispensed. The label should contain the following information:

1. Name and address of the facility
2. Client's name
3. Condition being treated
4. Date dispensed
5. Directions for use
6. Name, strength, and quantity of drug
7. Expiration date
8. Cautionary statement
9. Dispensing veterinarian
10. Withdrawal time

Client Relationship

Recommendations 9, 10, and 11 relate to relationships between the veterinarian and the livestock owner and his or her employees. Of necessity, this relationship requires honesty, openness, and a commitment to a common cause.

Some state laws govern drug storage and owner-records of treated animals. Such records also comply with FDA requirements for preserving the identity of animals treated with extra-label drugs.¹⁰

When drugs are to be used for extra-label purposes, additional written instructions should be provided to the livestock owner. Labels on containers may become dirty and blurred through repeated use. Sometimes, the drugs dispensed sit on the animal owner's shelves for long periods. The present drug delivery system is such that a particular drug may not be used entirely on the case for which it is dispensed. Instructions on the drug's use, withdrawal times, and precautions necessary should be included on the label of the dispensed drug, and additional written instructions also should accompany dispensed drugs. Suggested materials to accommodate these additional instructions are:

- 1) 8 1/2 x 11 inch clear plastic covers to allow placement of inserts containing the instructions for those drugs the livestock owner is permitted to have on hand. This covered sheet can be posted in the drug room area.
- 2) Loose-leaf notebooks that contain the instructions.
- 3) Computer printouts posted under plastic.

II

Recommended Guidelines for supervising the use and distribution of veterinary prescription drugs that are delivered to a livestock enterprise by lay distributors on the order of a veterinarian.

1. The order authorizing a licensed lay distributor to deliver veterinary prescription drugs to a specific livestock enterprise must be based on a valid veterinarian/client/patient relationship. The term "veterinary prescription drug" includes drugs labeled for use by or on the order of a licensed veterinarian and any other drugs used for purposes or dosages not described on the drug's label.

2. Veterinary orders for prescription drugs issued to clients to be distributed by a lay distributor should be written on a triplicate order form. The orders should be processed as follows: The veterinarian should retain the third copy in his/her records, the lay distributor should retain the original in his/her records, and the second copy should accompany the drugs delivered to the client.

3. The drug (prescription) order form should be designed to provide the following information:

A. The name and address of the client to whom the order is being delivered, with a statement signed by the client indicating that the client understands and will follow the directions given.

B. The name and address of the drug distributor to whom the order is being issued, with a statement signed by the distributor acknowledging that: a) only those drugs listed at the strength and quantity noted on the order will be provided; b) drugs will not be delivered after expiration of the order date; 3) the drug order will be processed exactly as written by the veterinarian and no substitutions of a different brand or product made without consulting the issuing veterinarian; 4) copies of all invoices documenting shipment of the drugs will be sent to the issuing veterinarian.

C. The name and address of the issuing veterinarian, including the veterinarian's license number and his/her statement that: a) a valid veterinarian/client/patient relationship exists with the client to whom the drugs are to be delivered; b) written instructions on the use of the drugs have been provided the client; c) the order may or may not be refilled, and if so, the numbers of refills.

D. Space should be provided for the name of the drug(s) to be delivered including the strength, and quantity. This should not be a check list or multiple choice list of drugs, but an actual listing of only those drugs to be delivered.

E. Space should be provided for written instructions on the use and withdrawal times of the drugs listed.

F. A statement that the order is void in ninety days from date of issue.

4. The drug order should be initiated from dialogue between the livestock owner, or his/her designated employee(s), and the issuing veterinarian. A request from the drug distributor to the issuing

veterinarian would not ordinarily be considered within the bounds of a valid veterinarian/client/patient relationship.

5. Telephone orders should be promptly reduced to writing by filling out the drug order form with subsequent processing being identical to written orders.

6. To the extent possible, orders for drugs to be delivered should be for drugs approved by the FDA.

7. Orders should be written only for drugs that can be legally obtained.

8. Orders for drugs should be written for minimal quantities needed for, at most, a three-month period.

9. Concerted effort should be made to instruct the clients that veterinary prescription drugs delivered should be stored securely on the farm or ranch, preferably under lock, with only minimal number of personnel on the farm or ranch having access to those drugs. Effort should be made to persuade each client to keep a complete record of all animals treated, including identification of animal(s), drug(s) used, amounts used, duration of treatment, and final disposition of the animal(s), i.e. date sold, returned to herd, or died.

10. Instructions for use of each veterinary prescription drug delivered should be written by the responsible veterinarian. These instructions should be posted or placed in the area on the owner's premises where the drugs are kept. These instructions, the drug storage area, and the drugs themselves should, if possible, be examined by the veterinarian and the client on a quarterly basis to assure cleanliness, orderliness, purity, and nonexpired dating.

11. The responsible veterinarian should keep records of the veterinary prescription drug orders written for at least three years.