

# Veterinary Therapeutics

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November 2012



AMERICAN VETERINARY MEDICAL ASSOCIATION

## **THE VETERINARIAN-CLIENT-PATIENT RELATIONSHIP**

The veterinarian-client-patient relationship (VCPR) is the basis for interaction among veterinarians, their clients, and their patients. A VCPR exists when all of the following conditions have been met:

- The veterinarian has assumed responsibility for making clinical judgements regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions.
- 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), or by medically appropriate and timely visits to the premises where the animal(s) are kept.
- The veterinarian is readily available, or has arranged for emergency coverage, for follow-up evaluation in the event of adverse reactions or the failure of the treatment regimen.

## **ADVERSE EVENT REPORTING**

**(Approved by the AVMA Executive Board in March 2006; reaffirmed April 2011)**

Being committed to the continuing availability of medicinal products that are pure, safe, potent and efficacious for animals, the AVMA encourages continued development and strengthening of adverse event reporting systems. This includes continued collaboration with constituent professional organizations, industry organizations, government entities and other stakeholders.

## **AMINOGLYCOSIDES**

**(Approved by the AVMA House of Delegates in March 1998; reaffirmed March 2004 and November 2008)**

Until further scientific information becomes available, aminoglycoside antibiotics should not be used in cattle, except as specifically approved by the FDA.

## **USE OF AQUATIC ANIMAL THERAPEUTIC AGENTS**

**(Approved by the AVMA Executive Board in June 2004; revised April 2007 and April 2012)**

The AVMA recognizes the need for sufficient approved therapeutics to facilitate safe and effective prevention, diagnosis, treatment and control of aquatic animal disease and:

- a) Supports the implementation of the Minor Use and Minor Species Animal Health Act of 2004;
- b) Cooperates with and, when appropriate, participate in realistic and responsible initiatives by other organizations to obtain the approval of new therapeutics for aquatic animals;
- c) Promotes the provision of educational information for veterinarians, producers and owners on relevant subjects related to aquatic animal therapeutics; and,
- d) Works with government agencies to develop appropriate policies and guidelines regarding the safe and effective use of aquatic animal therapeutics.
- e) Encourages a veterinarian-client-patient-relationship when drugs are used in all aquatic animals.

The following points should be considered with respect to the use of therapeutics in aquatic animal disease:

1. Prescription and Veterinary Feed Directive drugs  
Veterinarians are solely responsible for writing prescriptions and Veterinary Feed Directives for animal (including aquatic animal) drug treatment; however, there are very few approved drugs for aquatic animals. Therefore, in addition to the overall actions listed above, the AVMA will work to address this situation by:
  - a) Supporting and encouraging the responsible use of therapeutic agents in aquatic animals; and,
  - b) Supporting the promulgation of regulations that permit the extra-label use of drugs and medicated feeds for aquatic animals.
2. Non-prescription (“Over the Counter”) drugs  
The AVMA encourages veterinarians and aquatic animal owners to work closely together in the selection and use of approved or indexed drugs, as identified by FDA CVM, to ensure that these are administered in a manner consistent with:
  - a) The health needs of the aquatic animals;

- b) The product label and drug pharmacological properties;
  - c) Judicious use of antimicrobial drugs;
  - d) The safety of the animal, the user, and the surrounding environment; and,
  - e) Applicable regulations.
- 3. Unapproved Drugs  
The AVMA encourages appropriate action be taken to remove drugs that are being illegally marketed.
- 4. Veterinary Biologics  
The AVMA recognizes that infectious disease prevention can be achieved through the appropriate use of important health management alternatives to drugs, including veterinary biologics. The AVMA supports the central role that veterinarians play in the development, selection, administration and monitoring of veterinary biologics for aquatic animal disease prevention, diagnosis and control. The AVMA endorses the development and use of biologics and disease diagnostic tests for aquatic animals in accordance with USDA regulations for these products in other species.
- 5. Pesticides  
The AVMA recognizes that pesticides used to control life stages of parasites off the animal but in the environment are licensed through the Environmental Protection Agency and must be used in accordance with the label directions; that these products are often used without veterinary supervision; and that persons purchasing these products do not require a veterinary prescription.

The AVMA encourages veterinarians and aquatic animal owners or production facility managers to work together to ensure the responsible use of approved pesticides as part of an integrated pest control program.

The AVMA also recommends that non-veterinarians considering a pesticide treatment for an aquatic animal holding facility contact a veterinarian with experience in the management of aquatic animal diseases as an important step in the preparation of an appropriate integrated pest management plan.

## **USE OF BIOTECHNOLOGY IN DEVELOPMENT OF DRUGS AND VACCINES**

**(Approved by the AVMA Executive Board in November 1986; reaffirmed November 1989; reviewed March 2004; reaffirmed April 2008; revised April 2010)**

The AVMA supports and encourages the ethical use of biotechnology in veterinary medicine to develop new or improved biologic and therapeutic agents. Such use may include but is not limited to:

- Internationally harmonized research, development, production, licensure/approval, sale, distribution, and use of safe and effective vaccines, pharmaceuticals, and other therapeutic products used in animal health.
- Science-based regulatory policies and procedures supporting pre and post-approval product evaluations.
- Development of innovative, useful (sensitive, specific, and robust) diagnostic and surveillance tools.

## **AVMA GUIDELINES FOR COMPLEMENTARY AND ALTERNATIVE VETERINARY MEDICINE**

**(Approved by the AVMA House of Delegates in 2001; revised April 2006 and November 2007)**

### **Introduction**

These guidelines are intended to help veterinarians make informed and judicious decisions regarding medical approaches known by several terms including "complementary," "alternative," and "integrative." Collectively, these approaches have been described as Complementary and Alternative Veterinary Medicine (CAVM). The AVMA recognizes the interest in and use of these modalities and is open to their consideration.

The AVMA believes that all veterinary medicine, including CAVM, should be held to the same standards. Claims for safety and effectiveness ultimately should be proven by the scientific method. Circumstances commonly require that veterinarians extrapolate information when formulating a course of therapy. Veterinarians should exercise caution in such circumstances. Practices and philosophies that are ineffective or unsafe should be discarded.

## **Terminology**

The identification of standard and broadly accepted definitions applicable to CAVM, including the definition of CAVM itself, is challenging. These guidelines identify CAVM as a heterogeneous group of preventive, diagnostic, and therapeutic philosophies and practices. The theoretical bases and techniques of CAVM may diverge from veterinary medicine routinely taught in North American veterinary medical schools or may differ from current scientific knowledge, or both.

It is not the intent of these guidelines to determine or describe the relative value of the individual modalities. The evidence pertaining to, and the practice of, individual CAVM modalities differ. Current examples of CAVM include, but are not limited to, aromatherapy; Bach flower remedy therapy; energy therapy; low-energy photon therapy; magnetic field therapy; orthomolecular therapy; veterinary acupuncture, acuthery, and acupressure; veterinary homeopathy; veterinary manual or manipulative therapy (similar to osteopathy, chiropractic, or physical medicine and therapy); veterinary nutraceutical therapy; and veterinary phytotherapy.

## **Education, training, and certification**

The AVMA believes veterinarians should ensure that they have the requisite skills and knowledge for any treatment modality they may consider using. The AVMA does not officially recognize diplomate-status or certificates other than those awarded by veterinary specialty organizations that are members of the AVMA American Board of Veterinary Specialties (ABVS), nor has it evaluated the training or education programs of other entities that provide such certificates. Recognition of a veterinary specialty organization by the AVMA requires demonstration of a substantial body of scientific knowledge. The AVMA encourages CAVM organizations to demonstrate such a body of knowledge.

## **Recommendations for patient care**

The foremost objective in veterinary medicine is patient welfare. Ideally, sound veterinary medicine is effective, safe, proven, and holistic in that it considers all aspects of the animal patient in the context of its environment.

Diagnosis should be based on sound, accepted principles of veterinary medicine. Proven treatment methods should be discussed with the owner or authorized agent when presenting the treatment options available. Owner consent should be obtained prior to initiating any treatment, including CAVM.

Clients usually choose a medical course of action on the advice of their veterinarian. Recommendations for effective and safe care should be based on available scientific knowledge and the medical judgment of the veterinarian.

## **Responsibilities**

State statutes define and regulate the practice of veterinary medicine including many aspects of CAVM. These guidelines support the requisite interaction described in the definition of the veterinarian-client-patient relationship.<sup>1</sup> Accordingly, a veterinarian should examine an animal and establish a preliminary diagnosis before any treatment is initiated.

The quality of studies and reports pertaining to CAVM varies; therefore, it is incumbent on a veterinarian to critically evaluate the literature and other sources of information. Veterinarians and organizations providing or promoting CAVM are encouraged to join with the AVMA in advocating sound research necessary to establish proof of safety and efficacy.

Medical records should meet statutory requirements. Information should be clear and complete. Records should contain documentation of client communications and owner consent.

In general, veterinarians should not use treatments that conflict with state or federal regulations. Veterinarians should be aware that animal nutritional supplements and botanicals typically are not subject to premarketing evaluation by the FDA for purity, safety, or efficacy and may contain active pharmacologic agents or unknown substances. Manufacturers of veterinary devices may not be required to obtain premarketing approval by the FDA for assurance of safety or efficacy. Data establishing the efficacy and safety of such products and devices should ultimately be demonstrated. To assure the safety of the food supply, veterinarians should be judicious in the use of products or devices for the treatment of food-producing animals.

If a human health hazard is anticipated in the course of a disease or as a result of therapy, it should be made known to the client.

## **References**

1. Model Veterinary Practice Act, as published on the AVMA Website, [www.avma.org](http://www.avma.org)

## COMPOUNDING

(Approved by the AVMA Executive Board in November 2000; revised April 2005 and April 2009)

Compounding is the manipulation of a drug, other than in accordance with the FDA approved label, to make a different formulation of the drug to meet the needs of a specific patient.

Veterinarians need to be aware that compounding, including formulation in a novel drug delivery system (e.g. transdermal), may impact the absorption and depletion of a drug. This may result in drug concentrations that are above or below the therapeutic range and lead to the development of an adverse drug event, including therapeutic failure. In order to minimize the risk of adverse events associated with compounded drugs, the following actions are recommended:

1. The decision to use a compounded drug should be veterinarian (not pharmacist) driven, based on a veterinarian-client-patient relationship. Whenever possible the veterinarian should make that decision utilizing evidence-based medicine.
2. Compounding must be implemented in compliance with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Compliance Policy Guide 608.400 titled Compounding of Drugs for Use in Animals. Use of compounded drugs in food animals is accompanied by food safety concerns that preclude their use unless information exists to assure avoidance of illegal tissue residues.
3. Use of a compounded drug should be limited to:
  - a. Those drugs for which both safety and efficacy have been demonstrated in the compounded form in the target species;
  - b. Disease conditions for which response to therapy or drug concentration can be monitored; or
  - c. Those individual patients for which no other method or route of drug delivery is practical.
4. Use of a compounded drug should be accompanied by the same precautions followed when using an approved drug, including counseling of the client regarding potential adverse reactions and attention to the potential for unintended human or animal exposure to the drug.



One element in evaluating the quality of a compounding pharmacy is whether the pharmacy is accredited by an independent accreditation body. For example, the Pharmacy Compounding Accreditation Board (PCAB) offers accreditation to compounding pharmacies that meet high quality and practice standards. Further information and a listing of PCAB-accredited pharmacies are available at [www.pcab.org](http://www.pcab.org). Be aware that independent accreditation is different from association or professional training center memberships that may lack quality assurance programs and inspections.

## **COMPOUNDING FROM UNAPPROVED (BULK) SUBSTANCES**

**(Approved by the AVMA Executive Board in April 2005; revised November 2009)**

Compounding of drugs from unapproved (bulk) substances for use in non-food animals is medically necessary in certain situations and should be allowed through enforcement discretion, if such compounded products are used under the conditions for extra-label use of approved drugs delineated in the regulations written to implement AMDUCA. Such compounding should be allowed only if effective regulatory mechanisms are in place and implemented to assure that such compounding is patient specific and is performed only in the context of a veterinarian-client-patient relationship.

## **DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994**

**(Approved by the AVMA Executive Board in April 2001, reaffirmed March 2006 and April 2011)**

The AVMA supports the Food and Drug Administration Center for Veterinary Medicine's position that the Dietary Supplement Health and Education Act of 1994, which defines dietary supplements to be used in humans, does not apply to products intended for oral administration to animals. Additionally, the AVMA believes that the ACT should not be modified to include animals.

## **DRUG LABELING**

**(Approved by the AVMA Executive Board in April 2005, reaffirmed November 2009)**

Labels that accompany animal drugs should provide relevant pharmacokinetic and pharmacodynamic data necessary for the rational design of dosing regimens specific for the individual patient.

## **EXTRALABEL USE OF VETERINARY FEED DIRECTIVE DRUGS FOR MINOR SPECIES**

**(Approved by the AVMA Executive Board in April 2005; revised November 2006; reaffirmed April 2011)**

The AVMA believes that veterinarians, their clients and patients would be well served should the FDA CVM either amend the Compliance Policy Guide 615.115 (Extralabel Use of Medicated Feeds for Minor Species) or the Veterinary Feed Directive regulations (21 CFR Part 558) to accommodate extralabel use of all medicated feeds for minor species.

## **SALE OF HUMAN-LABEL DRUG PRODUCTS TO VETERINARIANS**

**(Approved by the AVMA Executive Board in July 1993; revised April 2001, June 2006, and April 2011)**

1. Because there are a limited number of drugs labeled for use in animals, veterinarians need to have access to human-labeled prescription drugs to effectively treat patients. As licensed health professionals, veterinarians must use them according to their best medical judgment in compliance with relevant laws and regulations.
2. The Food and Drug Administration has confirmed that veterinarians may legally obtain human-label prescription drugs; however, suppliers may not promote the sale of these products to veterinarians.
3. Veterinarians have the legal obligation to comply with AMDUCA regulations (21CFR530) when using any human or animal-labeled product for treatment of animals.

## **INTERNET PHARMACIES**

**(Approved by the AVMA Executive Board in April 2001; revised April 2005 and April 2009)**

The following recommendations are offered as a guide to prescribing and client purchases:

1. Drug therapy, when medically indicated, should be initiated by the attending veterinarian in the context of a veterinarian-client-patient relationship. Clients that wish to purchase their prescription drugs from a pharmacy rather than the veterinarian, should be advised to first obtain a prescription from their veterinarian before contacting a pharmacy. The veterinarian may choose to either issue the prescription in writing for the client, or contact the pharmacy electronically or by phone.
2. Drugs may be dispensed or prescribed. Veterinarians should honor client requests to prescribe rather than dispense a drug (AVMA Principles of Veterinary Medical Ethics). The client has the option of filling a prescription at any pharmacy.
3. One factor in evaluating the quality of an Internet pharmacy is accreditation by a recognized organization such as the National Association of Boards of Pharmacy (NABP). The NABP has developed the Vet-VIPPS program designed to ensure that Internet pharmacies that sell veterinary drugs are properly licensed and meet other program requirements. Further information is available at [www.napb.net](http://www.napb.net).
4. Veterinarians asked by pharmacies to approve prescriptions they have not initiated should do so only if the prescription is appropriate and a veterinarian-client-patient relationship exists.
5. It is within the veterinarian's (not the pharmacy's) purview to determine the medical criteria whereby a drug is indicated.
6. As with any prescription, a written record should be maintained.
7. Prescribing veterinarians should ensure that information regarding the proper use of the prescribed drug and the risks associated with its use are communicated to the client, regardless of the drug source.
8. If a client asks about obtaining drugs from a foreign country through an Internet source they should be aware that the importation and use of drugs not approved by the FDA is illegal.

## **THERAPEUTIC MEDICATIONS IN RACEHORSES**

**(Approved by the AVMA Executive Board in November 2010)**

The AVMA endorses the American Association of Equine Practitioners' policy on therapeutic medications in racehorses, which reads as follows:

"The AAEP policy on medication in pari-mutuel racing is driven by our mission to improve the health and welfare of the horse. The AAEP policy is aimed at providing the best health care possible for the racehorses competing while ensuring the integrity of the sport. The AAEP expects its members to abide by the rules of all jurisdictions where they practice. The AAEP condemns the administration of non-therapeutic or unprescribed medications to racehorses by anyone. The AAEP believes that all therapeutic medication should be administered to racehorses by or under the direction of a licensed veterinarian. Health care decisions on individual horses should involve the veterinarian, the trainer and owner with the best interests of the horse as the primary objective. The AAEP strongly encourages continued research in determining the therapeutic levels and appropriate withdrawal times that represent responsible use of medication in the racehorse. The AAEP is aware of the dynamics of the development of new products, as well as the continuing evaluation of current medications, and will continue to evaluate its policy based upon available scientific research and the best interests of the horse.

In order to provide the best health care possible for the racehorse, veterinarians should utilize the most modern diagnostic and therapeutic modalities available in accordance with medication guidelines designed to ensure the integrity of the sport. To this end, the following are the essential elements of AAEP policy concerning veterinary care of the racehorse:

- All racing jurisdictions should adopt the uniform medication guidelines set forth by the Racing and Medication Testing Consortium Inc. (RMTC). Including the RMTC testing procedures with strict quality controls and penalty schedules, these guidelines and procedures strive to protect the integrity of racing as well as the health and well-being of the horse.
- Race day medication must be in accordance with current RMTC guidelines. In the absence of a more effective treatment/preventative for exercise-induced pulmonary hemorrhage (EIPH), the AAEP supports the use of furosemide as a day-of-the-race medication to control EIPH. The AAEP advocates the research and development of new treatments to help prevent and/or control EIPH.
- The AAEP encourages proactive and constructive communication between regulatory bodies and practicing veterinarians and other industry stakeholders.
- The AAEP believes that all veterinarians should use judicious, prudent and ethical decisions in all treatments to ensure the health and welfare of the horse.

- The AAEP strongly endorses increased surveillance and enforcement of the above-mentioned regulations."

For more information regarding RMTTC guidelines, please visit [www.rmtcnet.com](http://www.rmtcnet.com).

## **PAIN IN ANIMALS**

**(Approved by the AVMA Executive Board in April 2001; revised November 2011)**

Animal pain and suffering are clinically important conditions that adversely affect an animal's quality of life. Drugs, techniques, or husbandry methods should be used to prevent, minimize, and relieve pain in animals experiencing or expected to experience pain. Protocols must be tailored to individual animals and should be based, in part, on the species, breed, age, procedure performed, degree of tissue trauma, individual behavioral characteristics, degree of pain, and health status of the animal.

## **PLURIPOTENT STEM CELLS**

**(Approved by the AVMA Executive Board in November 2005; revised June 2011)**

Pluripotent stem cells hold great potential for the development of new and exciting therapeutic strategies in the fight against diseases and injuries of animals and humans. Veterinarians have made fundamental contributions to the understanding of the biological potential and clinical use of stem cells, including early studies on mouse embryonic stem cells, derivation of the first human stem cell line, and foundation studies that led to the development of induced pluripotent stem cells. Research into the biology of animal and human stem cells continues to proceed at a breathtaking pace, although the full clinical potential of stem cell therapies remains years away. The AVMA recognizes the promising impact that research on stem cells will have on a diverse array of clinical applications in veterinary and human medical care.

Therefore, the AVMA takes the following position on the study and use of stem cells:

- The AVMA fully supports and encourages the ethical study of animal stem cells, including embryonic, induced pluripotent, and adult stem cells, as well as regenerative therapies achieved through directed transdifferentiation of somatic cells to defined precursors. Such studies, performed under the rigorous guidelines of the Animal Welfare Act, have enormous promise for the development of safe and effective cell-based therapies for the benefit of animal and human health.

- The AVMA endorses the use of stem cells in pre-clinical models of animal and human diseases. Such studies may minimize religious or political constraints associated with the use of human embryonic stem cells and facilitate critical advances in the use of pluripotent stem cells in the treatment of disease or injury common to humans and animals such as spinal injury or diabetes.
- The AVMA is in full accordance with the Guidelines for Human Embryonic Stem Cell Research as published in 2005 and modified in 2009 by the National Research Council and Institute of Medicine, National Academy of Sciences.
- The AVMA recognizes that the protection of animal welfare, as set forth in the Animal Welfare Act and by regulatory (eg, Public Health Service) and other recognized entities (eg, Association for Assessment and Accreditation of Laboratory Animal Care International [AAALAC]), must always apply during the course of research involving animals.
- The AVMA supports the use of stem cell therapies that have been demonstrated to be safe and effective to treat animal disease.

## **THERAPEUTIC MEDICATIONS IN NON-RACING PERFORMANCE HORSES**

**(The AVMA Executive Board approved endorsement in November 2003; reaffirmed endorsement November 2008 and November 2012)**

The AVMA endorses the American Association of Equine Practitioners' position on therapeutic medications in non-racing performance horses, which reads as follows:

"The AAEP policy on medication in non-racing performance horses is driven by our mission to improve the health and welfare of the horse. It is aimed at providing the best health care possible for horses competing under the current rules in various disciplines while ensuring the integrity of the sport. The AAEP expects its members to abide by the rules of all jurisdictions where they practice. The AAEP condemns the administration of non-therapeutic or unprescribed medications to performance horses by anyone. The AAEP believes that all therapeutic medication should be administered to performance horses by or under the direction of a licensed veterinarian. Health care decisions on individual horses involve the veterinarian, the trainer and the owner with the best interests of the horse as the primary objective.

The AAEP strongly encourages continued research in determining the therapeutic levels and appropriate withdrawal times that represent responsible use of medication in the competing horse. The AAEP is aware of the dynamics of the development of new products, as well as the continuing evaluation of current medications, and will continue to evaluate its policy based upon available scientific research and the best interests of the horse.

In order to provide the best health care possible for the performance horse, veterinarians should utilize the most appropriate diagnostic and therapeutic modalities in accordance with medication guidelines of the sport. To this end, the following are the essential elements of the AAEP policy concerning veterinary care of the performance horse:

- It is recognized that various performance horse disciplines have differing regulations concerning medication guidelines. The AAEP urges members to abide by these regulations and to work with the governing bodies to develop and enforce such regulations. The establishment of guidelines backed by testing procedures with strict quality controls should be the goal to protect the well being of the horse and the integrity of the sport
- The AAEP encourages proactive and constructive communication between regulatory bodies, practicing veterinarians and other industry stakeholders. The AAEP offers its expertise to all performance horse organizations for assistance in establishing medication guidelines for their respective disciplines.
- The use of medications for the purpose of stimulating, depressing or numbing a horse at the time of competition should be forbidden. It is recognized that some governing bodies allow for the emergency use of local anesthetics for strictly medical purposes within the normal withdrawal time for such agents. Such procedures must be very closely controlled.
- Products present in a horse at the time of performance that have been proven to interfere with accurate and effective post-performance testing should be strictly forbidden.
- The AAEP endorses the use of quality-controlled testing procedures by all performance horse organizations. Detection of pharmacologically insignificant levels of therapeutic medications should not constitute a violation of medication rules.

- Governing organizations have developed guidelines for the use of nonsteroidal anti-inflammatory agents in their sports. It is the opinion of the AAEP that the use of multiple NSAID agents is not in the best interest of the health and welfare of the horse. Performance horse governing bodies are encouraged to regularly reevaluate their regulations in light of this recommendation.
- The AAEP believes that all veterinarians should follow a judicious, prudent and ethical decision-making process.
- The AAEP endorses increased surveillance and enforcement of the above-mentioned regulations.”

## **GUIDELINES FOR VETERINARY PRESCRIPTION DRUGS**

**(Approved by the AVMA House of Delegates in 1998; revised April 1999, April 2005, March 2006, November 2006, and November 2010)**

### **Key Points**

- Veterinary prescription drugs are labeled for use only by or on the order of a licensed veterinarian. Incidents involving the sale and use of prescription drugs without a prescription should be reported to the proper state authority and the U.S. Food and Drug Administration.
- Veterinary prescription drugs are to be used or prescribed only within the context of a veterinarian-client-patient relationship (VCPR).
- Veterinary prescription drugs must be properly labeled before being dispensed.
- Appropriate dispensing and treatment records must be maintained.
- Veterinary prescription drugs should be dispensed only in quantities required for the treatment of the animal(s) for which the drugs are dispensed. Avoid unlimited refills of prescriptions or any other activity that might result in misuse of drugs.
- Any drug used in a manner not in accordance with its labeling should be subjected to the same supervisory precautions that apply to veterinary prescription drugs.

The AVMA has prepared the following guidelines as a resource regarding the use and distribution of veterinary prescription drugs. Veterinarians making treatment decisions must use sound clinical judgment and current medical information and must be in compliance with federal, state, and local laws and regulations.



## **Veterinary Prescription Drugs**

Veterinary prescription drugs are those drugs restricted by federal law to use by or on the order of a licensed veterinarian [Section 503(f) Food, Drug, and Cosmetic Act]. The law requires that the drug sponsor label such drugs with the statement: “Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

## **Veterinarian/Client/Patient Relationship**

A VCPR exists when all of the following conditions have been met:

- The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian’s instructions.
- 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) or by medically appropriate and timely visits to the premises where the animal(s) are kept.
- The veterinarian is readily available for follow-up evaluation, or has arranged for emergency coverage, in the event of adverse reactions or failure of the treatment regimen.

## **Veterinary Prescription Orders**

Orders issued by licensed veterinarians authorize drug distributors to deliver veterinary prescription drugs to a specific client, or authorize pharmacists to dispense such drugs to a specific client.

Veterinarians should assure compliance with relevant regulations (e.g. VCPR) of their State Board of Pharmacy and State Board of Veterinary Medicine, and applicable federal regulations.

## **Labeling and Record Keeping**

Adequate treatment records must be maintained by the veterinarian for at least two years (or as otherwise mandated by law), for all animals treated, to show that the drugs were supplied to clients with whom a VCPR has existed. Such records must include the information set forth under Basic Information for Records, Prescriptions, and Labels.

Food animal owners must also keep treatment records. Owner treatment records have been developed by several producer organizations and are available in conjunction with quality assurance programs.

All veterinary prescription drugs must be properly labeled when dispensed. A complete label should include all the information set forth under the section on Basic Information for Records, Prescriptions, and Labels.

#### Basic Information for Records (R) Prescriptions (P), and Labels (L)

- Name, address, and telephone number of veterinarians (RPL)
- Name (L), address, and telephone number of clients (RP)
- Identification of animal(s) treated, species and numbers of animals treated, when possible (RPL)
- Date of treatment, prescribing, or dispensing of drug (RPL)
- Name, active ingredient, and quantity of the drug (or drug preparation) to be prescribed or dispensed (RPL)
- Drug strength (if more than one strength available) (RPL)
- Dosage and duration
- Route of administration (RPL)
- Number of refills (RPL)
- Cautionary statements, as needed (RPL)
- Expiration date if applicable
- Slaughter withdrawal and/or milk withholding times, if applicable (RPL)
- Signature or equivalent (P)

The actual container must bear the veterinarian's name, address, name of the drug (active ingredient), identification of the animal(s) to be treated, adequate directions for proper use, and cautions/precautions including milk and meat withdrawal times. This information may be on the label applied by the manufacturer, or on a label attached to the product by the veterinarian.

If there is inadequate space on the label for any of the other required information, the veterinarian must provide the additional information on a separate sheet that accompanies the drug dispensed or prescribed.

State law and other regulations such as the Pasteurized Milk Ordinance may require more information than is stated in these guidelines. Specific label and record keeping information is required when drugs are prescribed for extralabel use (see the next section on AMDUCA).

When veterinary prescription drugs are dispensed to companion animal owners, the AVMA recommends that such drugs be placed in child-resistant containers. Such containers are mandated by law in certain states.

## **Handling, Storage and Disposal**

The veterinarian should inform clients to whom prescription drugs are delivered or dispensed about appropriate drug handling, storage, and disposal.

In the clinic, veterinary prescription drugs should be stored separately from over-the-counter drugs, and be easily distinguishable by the professional and paraprofessional staff. Drugs should be stored under conditions recommended by the manufacturer. All drugs should be examined periodically to ensure cleanliness and current dating.

Food animal clients should be advised that veterinary prescription drugs should be securely stored, with access limited to key personnel.

## **Animal Medicinal Drug Use Clarification Act (AMDUCA)**

### **Compliance in Veterinary Medical Practice**

With passage of the AMDUCA by Congress in 1994, the extralabel use of approved animal or human drugs in animals became a codified, FDA-regulated activity. Veterinarians may utilize drugs in an extralabel manner in their regular course of practice when the health of an animal is threatened or death may result from failure to treat. Under AMDUCA regulations, extralabel use means the actual or intended use of a drug, by or on the order of a veterinarian, in a manner that is not in accordance with approved labeling. Any deviation from the label, by veterinarians or lay persons is an illegal use, unless the use meets the requirements of AMDUCA. Deviations from the label include, but are not limited to:

- Use in a species not listed in the labeling.
- Use for indications not listed in the labeling.
- Use at dosage levels, frequencies or routes of administration other than those stated in the labeling.
- Deviation from the labeled withdrawal time based on these different uses.

Extralabel use is legal only when ordered by a veterinarian and within the context of a VCPR.

### **Guidelines for all animals:**

This document is intended to provide a summary of the AMDUCA requirements and does not list all the regulations that may apply. Veterinarians are strongly encouraged to familiarize themselves with the complete regulations. Information is available at [www.fda.gov/cvm](http://www.fda.gov/cvm).

AMDUCA regulations include but are not limited to the following:

1) Extralabel use is only allowed when the health of an animal is threatened, or suffering or death may result from failure to treat.

2) Record requirements-

- Identify the animals, either as individuals or a group.
- Animal species treated
- Number of animals treated
- Condition being treated
- The established name of the drug and active ingredient(s)
- Dosage prescribed or used
- Duration of treatment
- If applicable, specified withdrawal, withholding, or discard time(s) for meat, milk, eggs or animal-derived food.
- Keep records for a minimum of 2 years
- When requested, these records must be made available to FDA

3) Label requirements-

- Name and address of the prescribing veterinarian
- Established name of the drug(s)
- The class/species or identification of the animal or herd, flock, pen, lot or other group of animals being treated
- The dosage, frequency, route of administration and duration of therapy
- Any cautionary statements
- If applicable, veterinarian specified withdrawal, withholding or discard time for meat, milk, eggs or any other food

**Guidelines for extralabel use in food producing animals:**

In addition to the requirements for extralabel use in all animals there are regulations specific for food-producing animals.

Extralabel drug use is only allowed if there is no approved animal drug that is labeled for such use, or that contains the same active ingredient in the required dosage form and concentration. Alternatively, an approved animal drug exists, but a veterinarian finds, within the context of a veterinarian/client/ patient relationship, that the approved drug is clinically ineffective for its intended use.

It is important to note that AMDUCA does not permit extralabel use of drugs in animal feed. AMDUCA also does not permit extralabel drug use for production purposes.

Prior to prescribing or dispensing a food-animal drug for extralabel use the veterinarian must:

- Make a careful diagnosis and evaluation of the conditions for which the drug is to be used.
- Assure that the identity of the treated animal(s) is carefully maintained.
- Use appropriate scientific information to establish a substantially extended withdrawal period prior to marketing milk, meat, eggs or other edible products from the treated animals.
- Take appropriate measures to ensure that the recommended withdrawal times are met and no illegal drug residues occur.
- If there is insufficient scientific information available to determine a withdrawal interval, the veterinarian must not use the drug or the treated animal must not enter the food supply.

Use of a human drug, or an animal drug that is only approved for use in nonfood-producing animals, has further restrictions. These drugs are not permitted if a drug that is labeled for use in a food-producing animal can be used in a labeled or extralabel manner.

The extralabel use of certain drugs is prohibited in food animals. This list may be amended by the Food and Drug Administration. Thus, the following list is accurate as of the publication date of this document.

- Prohibited therapy in food animals: chloramphenicol, clenbuterol, diethylstilbestrol, dimetridazole, ipronidazole, other nitromidazoles, furazolidone, nitrofurazone, glycopeptides, fluoroquinolones.
- Prohibited therapy in lactating dairy cows: any sulfonamide except for approved uses of sulfadimethoxine, sulfabromethazine and sulfaethoxypyridazine.
- Prohibited therapy in female dairy cattle 20 months of age or older: phenylbutazone.
- Prohibited therapy in chickens, turkeys, and ducks: adamantane and neuraminidase inhibitor classes of drugs that are approved for treating or preventing influenza A.

### **Guidelines for extralabel use in nonfood-producing animals:**

AMDUCA also applies to medical decisions in nonfood producing animals. There is greater latitude for extralabel use in nonfood producing animals. However, the requirements stated above for “all animals” must still be followed. In addition, veterinarians should consider the following when treating nonfood-producing animals:

- Veterinarians may use approved animal and human drugs for therapeutic purposes in an extralabel manner so long as there is no threat to public health.
- An approved human drug may be used for treatment in an extralabel manner even when an identical, approved animal drug exists.
- Extralabel use of a drug labeled for another animal species can be used only if there is no approved, appropriate drug that is labeled for use in the patient's species or if an approved drug exists for the patient's species but is found by the veterinarian to be clinically ineffective.
- Extralabel use without a VCPR is illegal in all animals.

### **Guidelines for compounding of approved new animal and approved human drugs in all animals:**

Compounding from FDA-approved drugs is considered extralabel drug use under FDA rules.

Compounding is the customized manipulation of an approved drug(s) by either a veterinarian, or by a pharmacist upon the prescription of a veterinarian, to meet the needs of a particular patient. For example, mixing two injectable drugs is compounding. Preparing a paste or suspension from crushed tablets is another example of compounding. Likewise, adding flavoring to a drug is compounding.

Compounding is not allowed unless there is no approved new animal or approved new human drug that, when used per label or in an extra label fashion, can appropriately treat the condition diagnosed.

- Compounding must done by or under the order of a veterinarian.
- Compounded drugs must not be used for production or performance purposes.
- A compounded human drug cannot be used in a food-producing animal if a legally compounded animal drug can instead be used.
- Compounded drugs must be prepared from FDA-approved drugs
- The volume of compounded drug must be commensurate with the anticipated need for use in individual patients.
- State laws on compounding must also be followed.
- A veterinarian must be cognizant of the need to maintain a safe food supply. Specifically, veterinarians must not allow entry of a treated animal into the food chain, if there is insufficient scientific evidence indicating a proper withdrawal interval after treatment.

## **PET FOOD HEALTH CLAIMS**

**(Approved by the AVMA Executive Board in April 2008)**

The AVMA recognizes that the Food and Drug Administration (FDA) uses enforcement discretion in the oversight of certain pet food claims. Even though many of these foods could legally be considered drugs, certain claims are not FDA approved; consequently, efficacy for these products cannot be assured. Therefore:

- The AVMA encourages the pet food industry to act responsibly by only making health or therapeutic claims that are supported by quality scientific evidence.
- Veterinarians should assess relevant product information through principles of evidence-based medicine prior to using or recommending wellness or therapeutic pet foods.
- In the interest of pet safety, AVMA recommends the FDA require all pet food products with implied or explicit health or drug claims include a prominent statement on the label indicating that these claims have not been evaluated by the FDA.

## **UNAPPROVED NEW ANIMAL DRUGS MARKETING AS DEVICES**

**(Approved by the AVMA Executive Board in April 2007; reaffirmed November 2011)**

The AVMA encourages the FDA to take greater enforcement action in regulating the marketing of products represented as devices to the veterinary profession but that appear to be unapproved new animal drugs.

## **BEST MANAGEMENT PRACTICES FOR PHARMACEUTICAL DISPOSAL**

**(Approved by the AVMA Executive Board in July 2009)**

Minimize unused pharmaceuticals:

- Maintain close inventory control to decrease expired/unused drugs.
  - Write prescriptions for infrequently used drugs to prevent expirations.
  - Consider assigning responsibility for inventory control and disposal to one or a limited number of staff members.
  - Whenever possible, return drugs nearing expiration to the distributor.

Follow federal and state guidelines for disposal of controlled substances and hazardous waste.

Incineration typically provides the highest level of best management:

- Contract with an appropriate commercial disposal company. Sharps and medical waste disposal companies may be able to provide this service, depending on state regulations. Local human hospitals may have information on incineration companies or services available in the area.
- Use containers provided or recommended by the disposal company. The container should be leak-proof. Use of a leak-proof and tamper-resistant package will help prevent diversion. Add an absorbent substance such as kitty litter for liquids.
- For partially used liquids in syringes, place the needle in a sharps container, evacuate unused liquid pharmaceuticals into a leak-proof container containing an absorbent material such as kitty litter, and dispose of the syringe as appropriate medical waste.
- For drugs in a labeled package, blacken all personal information, place a large X over the product label but maintain the product identification, and place in a tamper-resistant and leak-proof container per incineration company guidelines.
- Label the container “For Incineration Only” to help prevent diversion.
- Maintain the pharmaceutical disposal container in a location away from client access, and consider storing filled containers in a locked storage area.

Consider landfilling if incineration is not feasible in the area:

- For partially used liquids in syringes
  - Squirt the remaining liquid into a container of kitty litter or other absorbent substance. Dispose of the syringe and needle as appropriate medical waste.
  - Seal it and dispose of it in a leak-proof bag.
- Blacken all personal information and place a large X over the product label but maintain product identification.
- Segregate from other types of waste and keep sealed in a leak-proof container.
- Use three layers of packaging to ensure the container does not leak.

Other important tips:

- Controlled substances and hazardous wastes (including chemotherapeutic agents and epinephrine) are handled differently from non-hazardous waste, and must be disposed of in accordance with federal and state laws. The services of a commercial company may be needed to comply with those laws.
- Never flush pharmaceuticals into the toilet or squirt down the sink.



- Never burn pharmaceutical waste unless authorized by federal and state regulations in an approved incinerator.
- Train all clinic employees on proper disposal of hazardous and non-hazardous waste.

Client education strategies:

- Educate clients on proper disposal – Inform clients that flushing unused pharmaceuticals is never appropriate.
- Be aware of return-for-disposal (take-back) programs in your area and encourage clients to participate.
- Dispense only the necessary quantity for appropriate treatment. Use refills rather than dispensing large quantities of a medication.

Be certain to check state and county laws and regulations for specific disposal requirements.

For questions or additional information please visit [www.avma.org](http://www.avma.org).

## **CLIENT DISPOSAL OF CONTROLLED SUBSTANCES**

**(Approved by the AVMA Board of Governors in March 2009)**

In response to the US Drug Enforcement Administration's consideration of controlled substance take-back programs that might be enacted for ultimate users (clients), the AVMA believes law enforcement agencies are the appropriate entities to undertake the safe disposal of such substances.

## **JUDICIOUS THERAPEUTIC USE OF ANTIMICROBIALS**

**(Approved by the AVMA Executive Board in November 1998; revised April 2004 and November 2008)**

### **Position Statement**

When the decision is reached to use antimicrobials for therapy, veterinarians should strive to optimize therapeutic efficacy and minimize resistance to antimicrobials to protect public and animal health.

### **Objectives**

Support development of a scientific knowledge base that provides the basis for judicious therapeutic antimicrobial use.

Support educational efforts that promote judicious therapeutic antimicrobial use.

Preserve therapeutic efficacy of antimicrobials.

Ensure current and future availability of veterinary antimicrobials.

## **Strategies**

Facilitate development and distribution of appropriate antimicrobial use guidelines by practitioner species-interest groups.

Improve scientifically based therapeutic practices through education.

## **Recognized Needs**

Improved monitoring and feedback systems for antimicrobial use and resistance patterns.

Research to improve scientifically based therapeutic practices.

## **Judicious Use Principles**

Preventive strategies, such as appropriate husbandry and hygiene, routine health monitoring, and immunization, should be emphasized.

Other therapeutic options should be considered prior to antimicrobial therapy.

Judicious use of antimicrobials, when under the direction of a veterinarian, should meet all requirements of a veterinarian-client-patient relationship.

Prescription, Veterinary Feed Directive, and extralabel use of antimicrobials must meet all the requirements of a veterinarian-client-patient relationship.

Extralabel antimicrobial therapy must be prescribed only in accordance with the Animal Medicinal Drug Use Clarification Act amendments to the Food, Drug, and Cosmetic Act and its regulations.

Veterinarians should work with those responsible for the care of animals to use antimicrobials judiciously, regardless of the distribution system through which the antimicrobial was obtained.

Regimens for therapeutic antimicrobial use should be optimized using current pharmacological information and principles.

Antimicrobials considered important in treating refractory infections in human or veterinary medicine should be used in animals only after careful review and reasonable justification. Consider using other antimicrobials for initial therapy.<sup>1</sup>

Use narrow spectrum antimicrobials whenever appropriate.

Utilize culture and susceptibility results to aid in the selection of antimicrobials when clinically relevant.

Therapeutic antimicrobial use should be confined to appropriate clinical indications. Inappropriate uses such as for uncomplicated viral infections should be avoided.

Therapeutic exposure to antimicrobials should be minimized by treating only for as long as needed for the desired clinical response.

Limit therapeutic antimicrobial treatment to ill or at risk animals, treating the fewest animals indicated.

Minimize environmental contamination with antimicrobials whenever possible.

Accurate records of treatment and outcome should be used to evaluate therapeutic regimens.

<sup>1</sup>In this context, this principle takes into account development of resistance or cross-resistance to important antimicrobials.

## **Glossary**

These terms are to be defined and utilized in the context of Judicious Therapeutic Use, with the intent of focusing on antimicrobials that may be of significance to human health. They are to be applied to the principles of Judicious Use outlined within the context of this document.

**Antibiotic**—a chemical substance produced by a microorganism which has the capacity, in dilute solutions, to inhibit the growth of or to kill other microorganisms.

**Antimicrobial**—an agent that kills microorganisms or suppresses their multiplication or growth.

**Broad Spectrum Antimicrobial**—a type of antimicrobial effective against a large number of bacterial genera; generally describes antimicrobials effective against both gram-positive and gram-negative bacteria.

**Narrow Spectrum Antimicrobial**—a type of antimicrobial effective against a limited number of bacterial genera; often applied to an antimicrobial active against specific families of bacteria.

**Antimicrobial Resistance**—a property of microorganisms that confers the ability to inactivate or elude antimicrobials or a mechanism that blocks the inhibitory or killing effects of antimicrobials.

**Extralabel Use**—actual or intended use of a drug under veterinary direction in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling; use for indications (disease or other conditions) not listed in the labeling; use at dosage levels, frequencies, or routes of administration other than those stated in the labeling; and deviation from the labeled withdrawal time based on these different uses.

**Immunization**—the process of rendering a subject immune or of becoming immune, either by conventional vaccination or exposure.

**Monitoring**—periodic health surveillance of the population or individual animal examination.

**Therapeutic**—treatment, control, or prevention of disease.

**Veterinarian-Client-Patient Relationship (VCPR)**—exists when all of the following conditions have been met:

1. The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions.
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) 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 evaluation or has arranged for emergency coverage in the event of adverse reactions or failure of the treatment regimen.

**Veterinary Feed Directive (VFD) Drug**—category of medicated feeds created by the Animal Drug Availability Act of 1996 to provide an alternative to prescription status for certain therapeutic animal pharmaceuticals for use in feed. Any animal feed bearing or containing a VFD drug shall be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian in the course of the veterinarian's professional practice.



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