

Veterinary Therapeutics

APRIL 2009



AMERICAN VETERINARY MEDICAL ASSOCIATION

ADVERSE EVENT REPORTING

(Approved by the AVMA Executive Board March 2006)

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 AVMA House of Delegates March 1998; COBTA reaffirmed March 2004, November 2008)

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

AQUATIC ANIMAL THERAPEUTIC AGENTS

(Approved by AVMA Executive Board, June 2004; revised April 2007)

Aquatic Animal Therapeutic Agents

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.

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 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. 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.

4. 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 VETERINARY MEDICINE AND ANIMAL AGRICULTURE

(Approved by the AVMA Executive Board, April 2007)

Humans have altered animals, plants, and even microbes through selective breeding for millennia, to the great benefit of society. Biotechnology increases our ability to continue this process at an accelerated pace and in a more directed manner. With these powerful tools comes an increased ability to do great good but there are risks and benefits to the technology. Although it is imperative that biotechnology be used responsibly and ethically, it is equally important that these powerful techniques for advancement not be sequestered due to unfounded fear of potential adverse consequences.

The AVMA supports the opportunity to use biotechnology for a variety of applications including:

- The benefit and protection of public health (human, animal, and environmental) and welfare
- Enhancing infectious disease resistance and eliminating genetic-based diseases
- Increased efficiency of food and fiber production
- Improving the utility, nutritional value, and safety of human food and animal feeds
- The production of improved animal medicinal products and diagnostic tools
- The improvement and protection of the environment, and
- The mitigation of the environmental impact of crop and agricultural animal production.

The AVMA affirms the responsible use of biotechnology to improve animal and human health.

The creation of new genetic-based knowledge through basic genetic research and the practical application of that knowledge should not be restricted so long as it does not negatively impact the integrity of the environment and the health, safety, and well being of the resulting animals, the animals receiving or consuming the resulting products, or the consumers of animal products. The AVMA supports a science-based regulatory policy for the approval of products

developed through biotechnology. Current regulations require evaluation of product safety and efficacy by USDA, FDA, EPA, or other appropriate government agencies before they can be marketed for the intended uses. Future evaluations should be solidly based on sound science and meaningful risk assessments.

AVMA GUIDELINES FOR COMPLEMENTARY AND ALTERNATIVE VETERINARY MEDICINE

(Approved by AVMA House of Delegates 2001; revised by the AVMA Executive Board April 2006, 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.¹ 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

COMPOUNDING

(Approved by the Executive Board November 2000; revised by the Executive Board April 2005; 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. 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 Executive Board April 2005)

Compounding of drugs from unapproved (bulk) substances for use in non-food animals is medically necessary in certain situations and should be allowed through regulatory 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 Executive Board April 2001, Executive Board reaffirmed in March 2006)

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 Executive Board April 2005)

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

(Developed by AVMC March 2005 and Executive Board Approved April 2005; revised November 2006)

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.

HUMAN-LABEL DRUG PRODUCTS, SALE TO VETERINARIANS

(Executive Board July 1993; amended April 2001, amended June 2006)

1. Veterinarians, as licensed health professionals, need to have access to human-labeled prescription drugs to effectively treat animals and 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 AVMA Executive Board April 2001; revised by Executive Board April 2005; 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.

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 June 2001; reaffirmed June 2007)

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 under the current rules of racing in jurisdictions throughout the United States and Canada 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 the AAEP policy concerning veterinary care of the racehorse:

- All racing jurisdictions should adopt uniform medication guidelines, testing procedures with strict quality controls and penalty schedules that strive to protect the integrity of racing as well as the health and well being of the horse.
- Stimulants, depressants and local anesthetics or other numbing agents present in a horse at the time of a race should be strictly forbidden.
- Products present in a horse at the time of a race that have been proven to interfere with accurate and effective post-race testing should be strictly forbidden.
- Detection of pharmacologically-insignificant levels of therapeutic medications should not constitute a violation of medication rules.
- No medication should be administered on the day of the race with the exception of furosemide (Lasix®). In the absence of a more effective treatment for exercise-induced pulmonary hemorrhage, the AAEP supports the use of furosemide as a day-of-the-race medication for certified bleeders.
- 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 endorses increased surveillance and enforcement of the above-mentioned regulations."

PAIN IN ANIMALS

(Current as of June 2005)

The AVMA believes that animal pain and suffering are clinically important conditions that adversely affect an animal's quality of life. Drugs, techniques, or husbandry methods used to prevent and control pain 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.

STEM CELLS

(Approved by the Executive Board November 2005)

Stem cells hold great promise for the development of new and exciting therapeutic strategies in the fight against diseases and injuries of animals and humans. Since 1998, when a veterinarian became the first person to derive and propagate pluripotent stem cells from human embryos, research into the biology of animal and human stem cells has proceeded at a breathtaking pace. The AVMA recognizes the enormous impact that research on stem cells will have on ultimately leading to a potentially 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 and use of animal stem cells for the benefit of animal and human health;
- The AVMA is in full accordance with the "Guidelines for Human Embryonic Stem Cell Research" as published in 2005 by the National Research Council and Institute of Medicine, National Academy of Sciences (<http://books.nap.edu/catalog/11278.html>);
- 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 (eg, National Institutes of Health) agencies, must always apply during the course of research involving the mixing of animal (eg, mouse) and human stem cells and/or other biological products in scientifically valid experimental procedures (eg, production of chimeras, use of animal-derived feeder cells); and
- The AVMA affirms that the study and use of therapeutic and reproductive cloning using animal stem cells for the benefit of animal health and welfare be conducted according to ethical principles of veterinary medicine.

THERAPEUTIC MEDICATIONS IN NON-RACING PERFORMANCE HORSES

(Approved by the Executive Board, November 2003, reaffirmed November 2008)

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.”

US BANNED DRUGS USED BY EXPORTING COUNTRIES

(Approved by the Executive Board November 2001; amended November 2005)

The AVMA urges the Food and Drug Administration to implement import regulations consistent with existing domestic bans on the use of certain drugs in food animals in the United States. The banned drugs are chloramphenicol, diethylstilbesterol, dimetridazole, ipronidazole, furazolidone, nitrofurazone, and enrofloxacin for use in turkeys and chickens.

GUIDELINES FOR VETERINARY PRESCRIPTION DRUGS

(Approved by the AVMA House of Delegates 1998; revised by the Executive Board April 1999; revised by the Executive Board April 2005; revised by the Executive Board March 2006; revised November 2006)

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 (extralabel use) 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 of their State Board of Pharmacy and State Board of Veterinary Medicine.

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 and Storage

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

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 Drug Use

The therapeutic administration of any approved dosage form drug in a manner that is not in accordance with the drug's labeling requires additional management. AMDUCA regulations are in force for all approved therapeutic dosage form drugs if administered in a manner not in accordance with the drug's labeling. For such usage, the FDA specifies that the following criteria must be met:

- Make a careful diagnosis and evaluation of the conditions for which the drug is to be used.

- 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.
- Assure that the identity of the treated animal(s) is carefully maintained.
- Establish a substantially extended withdrawal period supported by appropriate scientific information prior to marketing milk, meat, eggs, or other edible products from the treated animal(s).

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, other nitrofurans, glycopeptides.
- Prohibited therapy in food animals except approved uses: fluoroquinolone class of antibiotics.
- Prohibited therapy in lactating dairy cows: any sulfonamide except for those specifically approved (sulfadimethoxine, sulfabromothiazine and sulfaethoxyypyridazine).
- 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.

When dispensing or prescribing drugs for extralabel use one should follow the normal labeling and record keeping guidelines stated above, but also be aware AMDUCA regulations require the following:

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.

- Specified withdrawal, withholding, or discard time(s), if applicable, for meat, milk, eggs or animal-derived food.
- Keep records for a minimum of 2 years.
- FDA may have access to these records to estimate risk to public health.

Label requirements-

- Name and address of the prescribing veterinarian.
- Established name of the drug.
- Any specified directions for use including the class/species or identification of the animal or herd, flock, pen, lot, or other group; the dosage frequency, and route of administration; and the duration of therapy.
- Any cautionary statements.
- Veterinarian specified withdrawal, withholding, or discard time for meat, milk, eggs, or any other food.

AMDUCA does not permit extralabel use of drugs in feed.

Compounding is defined as any manipulation to produce a dosage form drug other than that manipulation that is provided for in the directions for use on the labeling of the approved drug product. A few examples include combining drug agents for anesthesia, incorporating a tablet into reduced dosage liquid or capsule forms, or creating certain antidotes.

Guidance is found in FDA-CVM Compliance Policy Guide 608.400
 “Compounding of Drugs for Use in Animals.”

PET FOOD HEALTH CLAIMS

(Approved by the AVMA Executive Board, 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 MARKETED AS DEVICES (Approved by the AVMA Executive Board, April 2007)

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.



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