



### DRUG USE GUIDELINES FOR BOVINE PRACTICE

*These guidelines from the American Association of Bovine Practitioners serve to assist the veterinarian in ensuring that drugs used in cattle are used in a safe and responsible manner.*

Good animal husbandry and preventive measures and care are vital to keeping cattle healthy and are important in reducing medical interventions, including the use of drugs. However, when FDA-approved pharmaceuticals need to be used in the care and treatment of cattle, they must be used in a legal and proper manner by veterinarians and their clients to protect animal health and the food supply.

The keys to appropriately using drugs in bovine practice include establishing and maintaining a veterinarian-client-patient relationship (VCPR), utilizing scientific knowledge and veterinary training, prescribing/dispensing drugs appropriately, providing drug use oversight on cattle operations, preventing residues, avoiding unapproved products, prudently using antimicrobials and appropriately using analgesics.

#### **ESTABLISH AND MAINTAIN A VCPR**

As outlined in the AABP Guideline, "Establishing and Maintaining the Veterinarian-Client-Patient Relationship in Bovine Practice," the following areas are critical: a mutual agreement that a VCPR exists, a veterinarian of record with oversight, clear relationships with consultants and other veterinarians, written treatment protocols, written or electronic treatment records, and provision of drugs for only specific time frames and for specific protocols.

For more information, refer to AABP's VCPR guidelines (see Resources below).

#### **USE SCIENTIFIC KNOWLEDGE AND VETERINARY MEDICAL TRAINING**

Veterinarians should use their scientific knowledge concerning disease management, diagnostics, epidemiology and pharmacology to work with cattle owners and managers to aid in disease prevention, control and management.

Appropriate clinical and laboratory diagnostics should be used when applicable to diagnose disease in cattle prior to making decisions about drug use. It

is also important to establish and maintain records of clinical and laboratory findings.

#### **PROVIDE OVERSIGHT ON DRUG USE ON CATTLE OPERATIONS**

Protocols should be developed jointly with clients and placed in appropriate written or other non-verbal form for use by the operation's personnel. Designated personnel should be trained to identify clinical signs and reasons for drug administration along with correct administration, handling and storage of drugs on the operation to promote efficacy and prevent adverse reactions, residues, damage to or inactivation of the drug properties and to comply with state and federal regulations.

There also should be agreed-upon review intervals appropriate to the scope and scale of an operation because procedural drift can occur due to employee turnover, lack of consistent oversight and other factors, which can have major impacts on proper drug use. Veterinarians are in a key position to monitor not only what drugs are being used on a cattle operation, but how correctly and effectively they are being used by designated personnel.

#### **PRESCRIBE OR DISPENSE DRUGS IN A LEGAL AND ETHICAL MANNER**

Veterinarians should know and understand state and federal laws and regulations about administering, dispensing, and prescribing drugs. The relevant laws and regulations include the Animal Medicinal Drug Use Clarification Act (AMDUCA) for extralabel use, the Controlled Substances Act, state pharmacy acts, and state veterinary practice acts. Of salient importance is knowledge of prohibited extralabel uses of drugs in cattle: feed additives may not be used extralabel, extralabel use of drugs for production purposes is illegal, and certain drugs are always prohibited from extralabel use in cattle (see Resources below).

All drugs should have a label that indicates the



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active ingredients, the amount of drug, concentration, instructions for use, and withdrawal time(s). The Food Animal Residue Avoidance Databank (see Resources) may be able to provide withdrawal time estimates for extralabel uses. The exact contents of the label and the need for additional veterinary directed labeling will depend on the distribution channel and federal and state labeling requirements for the particular type of cattle operation where the drug is being used.

The recording and maintenance of clinical and laboratory findings are essential for understanding disease within a given animal population. Review of these data should be performed on a regular basis to determine if changes in the disease management program are needed.

In addition to legal requirements, veterinarians are reminded of their ethical responsibilities to not dispense, recommend or prescribe drugs solely for purposes of income generation.

For drugs that are fed to cattle, there are particular rules that must be complied with. For medically important antimicrobial drugs, FDA's Guidance For Industry (GFI) #213 (see Resources) was published in the Federal

Register December 12, 2013. This initiated a three-year period to adopt the changes in GFI #209 (see Resources), which are that all medically important antimicrobial drugs will transition from over-the-counter (OTC) to Veterinary Feed Directive (VFD) drugs for feed additives and from OTC to prescription status for drugs used as water medications, and that all growth promotion labels of antimicrobials shall be withdrawn. The regulations for VFD drugs are expected to be finalized in the first half of 2015. Cattle veterinarians will provide the veterinary oversight for VFD drugs administered by their clients beginning by the end of 2016. It will be important for those who will be prescribing VFD drugs to remain current on the upcoming changes.

#### PREVENT VIOLATIVE RESIDUES

Veterinarians should have an understanding of drugs and their labels including production class, dose, duration, route and frequency of administration and withdrawal times to avoid violative milk and meat residues. They should verify their client and the operation's personnel also understand the prescribing information to avoid residues.

Treated animals should be appropriately identified, and when indicated, segregated from non-treated animals such as milking strings or groups of animals leaving the operation for slaughter before the treated animal's withdrawal period is over.

Treatments should be recorded and the record should include the person(s) administering and/or recording the treatment, date, diagnosis, treatment given, dosage, route of administration, withdrawal date (or dates if both meat and milk are involved) and animal identification. These records should be kept for a minimum of two years and should be readily retrievable.

#### AVOID COMPOUNDED AND UNAPPROVED DRUGS

The use of drugs compounded from bulk ingredients in cattle is currently illegal. FDA has exercised enforcement discretion when compounding from bulk ingredients in the case of certain poison antidotes

#### WHAT IS AN ANIMAL DRUG?

21 USC 321 defines an animal drug as: (g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.



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and euthanasia agents (refer to the Compliance Policy Guideline on compounding and its Appendix). In the case of euthanasia, see the AABP Guidelines for Euthanasia reference below.

Compounding from bulk ingredients to manufacture other medications for cattle under any circumstance is inappropriate. There are circumstances, however, where minor compounding might be considered appropriate under the AMDUCA algorithm, i.e. vitamin B-12 in a bottle of dextrose. The AMDUCA regulations state that compounded preparations are required to be prepared from FDA-approved animal or human drugs, and that if possible, an animal-labeled drug is to be used for compounding rather than a human-labeled drug.

Drugs that are not approved for cattle or that are not approved for the production class of cattle being treated should only be used after following AMDUCA regulations. Medications that are labeled for cattle or for that production class should always be considered first for treatment, control and prevention of disease. If the prescribing veterinarian has determined that the labeled medication is or will be clinically ineffective for the disease condition being treated, and extralabel use is indicated, then an extended withdrawal period for meat and milk should be provided. The Food Animal Residue Avoidance Databank (FARAD) may be of help in establishing these recommendations (see Resources below).

The labeled withdrawal period from the manufacturer does not apply if the drug is used in an extralabel manner such as changing the dose, route, duration, frequency or production class of animal. The FDA considers the use of medications in a production class of animal not approved on the label to be an extralabel use. When a veterinarian prescribes this extralabel use in an unapproved class of livestock, there is no tolerance in edible tissues or milk. Any detectable level of the medication in such a scenario is a violative residue. Therefore, the withdrawal time for meat and milk must be significantly extended to ensure there

#### PROHIBITED/ILLEGAL DRUGS IN CATTLE

**CEPHALOSPORINS** Certain prohibitions of extralabel use of cephalosporins in cattle were instituted by the FDA in April 2012. A veterinarian can prescribe and use cephalosporins for treatment or control of an indication/disease that is not on the label as long as the dose, route, frequency, production class and duration label uses are followed. Cephapirin is exempted from this prohibition. Furthermore, it is illegal to use a cephalosporin that is not labeled for cattle; therefore, only the FDA approved products for cattle are legal to use.

**FLUOROQUINOLONES** The FDA prohibits all extralabel use of fluoroquinolones in cattle. All such uses are illegal.

**SULFA DRUGS IN LACTATING DAIRY CATTLE** The FDA prohibits the extralabel use of sulfa drugs in lactating dairy cattle. The FDA defines a lactating dairy cow as a dairy breed animal 20 months of age or older, regardless of lactation state. Therefore, use of a sulfa drug other than sulfadimethoxine (at label dosing regimen, for label indications) in a female dairy animal 20 months of age or older is illegal.

**PHENYL BUTAZONE** The FDA prohibits the use of phenylbutazone in female dairy breed animals 20 months of age or older. All uses of phenylbutazone in female dairy animals 20 months of age or older are illegal.

**DIETHYLSTILBESTEROL (DES)** The FDA prohibits the extralabel use of DES in cattle. Currently there are no DES products approved for cattle; therefore, use of any DES in cattle is illegal.

**FEED GRADE ANTIBIOTICS** The FDA prohibits the extralabel use of drugs in feed for cattle. These drugs can only be used for the indication, production class, dose, frequency and duration that is stated on the FDA approved label. All extralabel use is illegal. Milk replacer is considered to be feed; therefore, this prohibition applies to drugs that are placed in milk replacer as well. (See Resources for Prohibited Drug List)

#### DRUGS OR USES NOT RECOMMENDED IN CATTLE

**FLUNIXIN MEGLUMINE** This NSAID is labeled to be used by the intravenous route only. Use by other routes is never appropriate and can lead to extended withdrawal times as well as causing tissue damage that is contrary to Beef Quality Assurance guidelines.

**AMINOGLYCOSIDES** The AABP, the American Veterinary Medical Association, the Academy of Veterinary Consultants and the National Cattlemen's Beef Association have position statements against the extralabel use of aminoglycosides in cattle due to prolonged withdrawal times. Extralabel use of aminoglycosides in any production class of cattle is strongly discouraged.

*For further information, refer to the Animal Medicinal Drug Use Clarification Act (1994).*





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is no detectable level of residue in the animal product. When an appropriate withdrawal time cannot be established, use of the drug precludes the animal or its products from entering the food chain.

#### ASSURE RESPONSIBLE USE OF ANTIMICROBIALS

The ability of antimicrobial drugs to treat bacterial disease is a societal resource. Veterinarians working with cattle have the responsibility to use antimicrobial drugs appropriately and to provide oversight of antimicrobial drug use by their clients. Antimicrobials should only be employed as part of a well-defined, prevention-based disease management program.

A veterinarian should first consider if an antimicrobial is necessary and appropriate. Additionally, the veterinarian should consider if another intervention may be more effective for disease prevention or therapy. If an antimicrobial is deemed necessary, an antimicrobial which has been shown to be safe and effective for the diagnosed condition should be used. Safety considerations include the animal(s), the environment, and food the animals are producing. Efficacy means that specific outcomes are defined and evaluated by research data. Diagnosed means that the components of a case definition have been met.


When the selected antimicrobial is in use, there must be a sustained commitment to use the antimicrobial in the manner in which safety and efficacy have been demonstrated. This requires an ongoing relationship

between the veterinarian, the client and the patient(s). In this relationship, the veterinarian should continue to evaluate the need for, and the results of, the antimicrobial use. The veterinarian should also evaluate alternatives, including management practices, which may reduce the need for antimicrobial therapy.

The AABP has partnered with the AVMA to develop more specific guidelines for prudent antimicrobial use (see Resources below).

#### USE ANALGESICS TO CONTROL PAIN WHEN INDICATED

In the U.S., no drugs are currently approved for pain alleviation in cattle. AMDUCA provides for the extralabel use of drugs when labeled drugs are not available, which means the lack of approved products does not remove the responsibility of veterinarians to provide pain relief when it is indicated. It is not the purpose of these guidelines to outline all painful procedures and conditions for which analgesia might be indicated, but the AABP has produced guidelines for castration and dehorning. Principles of animal welfare, medical knowledge and diagnostic capabilities should guide the use of analgesics for other painful conditions and procedures encountered in veterinary practice.

More specific information on implementing pain relief measures for castration and dehorning can be found in the AABP Castration and Dehorning Guidelines (see Resources below). 

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#### RESOURCES

##### American Association of Bovine Practitioners' Guidelines

- *Castration and Dehorning Guidelines* [http://aabp.org/resources/AABP\\_Guidelines/Castration\\_and\\_DeHorning\\_Guidelines\\_app3.2014\\_03.17.2014.pdf](http://aabp.org/resources/AABP_Guidelines/Castration_and_DeHorning_Guidelines_app3.2014_03.17.2014.pdf)
- *Veterinarian Client Patient Relationship (VCPR) Guidelines* [http://aabp.org/resources/aabp\\_guidelines/vcprguidelinefinal11-2013.2.pdf](http://aabp.org/resources/aabp_guidelines/vcprguidelinefinal11-2013.2.pdf)

##### FDA Center for Veterinary Medicine

- *Unapproved Drugs* <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UnapprovedAnimalDrugs/default.htm>
- *Drugs Prohibited for Extralabel Use in Animals* <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=530.41>
- *Judicious Use of Antimicrobials* <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm>

- *AMDUCA* <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdca/significantamendments/tothefdcact/animalmedicinaldruguseclarificationactamducaof1994/default.htm>

- *FDA Guidance for Industry #209* <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf>

- *FDA Guidance for Industry #213* <http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm299624.pdf>

##### American Veterinary Medical Association

- *AVMA/AABP Prudent Use Guidelines* <https://www.avma.org/KB/Policies/Pages/AABP-Prudent-Drug-Usage-Guidelines-for-Cattle.aspx>
- *Extralabel Drug Use Algorithm* <https://www.avma.org/KB/Resources/Reference/Pages/AMDUCA2.aspx>

**Food Animal Residue Avoidance Databank (FARAD):** <http://farad.org/>