AASRP GUIDELINES

# THERAPEUTIC DRUG USE GUIDELINES FOR SMALL RUMINANT PRACTITIONERS

Good animal husbandry and preventive care are key to maintaining the health of small ruminants. When health is threatened, the use of therapeutic drugs may be needed. These guidelines provide best practices for prescribing and administering therapeutic drugs to small ruminant patients in a legal and ethical manner that protects the food supply.

- Establish and maintain a Veterinarian-Client-Patient Relationship (VCPR).[1] Best practices for herd-level VCPRs include maintaining, in writing, the following documents: Veterinarian-of-Record designation, treatment protocols and treatment records.
- Use scientific knowledge and veterinary medical training to guide therapeutic drug use decisions. Veterinarians should apply their training and continuing education in epidemiology, diagnostics, pharmacology, and disease management to aid small ruminant owners in disease prevention, control and treatment.
- Provide oversight on drug use for small ruminant owners/caretakers. Veterinarians should continually review written protocols, provide training and re-training of individuals providing treatments, ensure proper storage and handling of drugs, and ensure withdrawal times are communicated and observed.
- Prescribe or dispense drugs in a legal and ethical manner. Veterinarians must follow relevant local, state and federal laws and regulations, including state veterinary and pharmacy practice acts, the Animal Medicinal Drug Use Clarification Act (AMDUCA) and Controlled Substances Act. Important restrictions on extralabel

## WHAT IS AN ANIMAL DRUG?

The Federal Food, Drug and Cosmetic Act 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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use are described below. Drugs should always be labeled with active ingredients, the amount of drug, concentration, instructions for use and withdrawal time(s). Other label requirements may be specified by state veterinary practice acts, pharmacy practice, or other laws, and by other entities such as professional or producer organizations.

- Do not administer drugs compounded from bulk or unapproved drugs. Drugs compounded from bulk are not permitted in food animal species, although the use of specific antidotes is likely to be of low regulatory priority. Unapproved drugs are drugs not approved for any species by the Food and Drug Administration (FDA) and are illegal to prescribe or use. Administration of compounds that may otherwise be generally recognized as safe but as a drug, i.e., intended to treat, prevent, control or mitigate disease, is not permitted under federal law.
- Assure responsible use of antimicrobial drugs.[2] Antimicrobial stewardship includes preventing common diseases through management strategies, using evidence-based approaches to make decisions about antimicrobial therapy, and using antimicrobials judiciously and sparingly and with evaluation of outcomes.
- Use analgesics to control pain when indicated.[3]
- Prevent violative residues.[4] When labeled drugs are available, the label withdrawal time should be followed. When drugs must be used extralabel, AMDUCA provisions must be followed, and the treating veterinarian is responsible for providing an adequate extended withdrawal interval. A specialty consulting service, such as the Food Animal Residue Avoidance Databank (FARAD), should be contacted to assist in determining an appropriate extended withdrawal interval.

## SELECT PROHIBITED AND ILLEGAL DRUGS IN SHEEP, GOATS AND CERVIDS

- Extralabel uses of fluoroquinolones is prohibited in food animals. There are currently no approved fluoroquinolones for sheep, goats or cervids in the U.S., so their use in these species is illegal.
- The ban on extralabel use of cephalo-sporins in major food animal species does not apply to sheep, goats and cervids because they are minor species. However, other provisions of the principles of AMDUCA still apply.
- Extralabel use of sulfonamide drugs and phenylbutazone in lactating dairy sheep or goats is not specifically banned, but their use in lactating animals may be a higher regulatory priority since extralabel use of sulfonamides and phenylbutazone in lactating dairy cows is illegal.
- All feed-grade antimicrobials and other feed additives must be used as labeled. While there is no legal extralabel use of medicated feeds, CPG 615.115 outlines the process by which medicated feeds can be used in minor food animal species without legal action by the FDA CVM.

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## REFERENCES

[1] See AASRP VCPR Guidelines http://aasrp.org/about/guidelines/VCPR2020.pdf
[2] See AASRP Guidelines for Antimicrobial Stewardship and Judicious Antimicrobial Use in Small Ruminant Practice
[3] See AASRP Guidelines for Dehorning and Tail Docking in Sheep and Goats
[4] See AASRP Position Statement on Small Ruminants as Food Animals

## ADDITIONAL RESOURCES

**FDA Center for Veterinary Medicine**

- Animal Drugs at FDA: https://animaldrugsatfda.fda.gov/adafda/views/#/search
- CPG 615.115 Extralabel Use of Medicated Feeds for Minor Species: https://www.fda.gov/media/71960/download
- Blue Bird Labels: https://animaldrugsatfda.fda.gov/adafda/views/#/blueBirdLabels
- Antimicrobial Resistance: https://www.fda.gov/animal-veterinary/safety-health/antimicrobial-resistance
- Compounding Animal Drugs from Bulk Drug Substances Draft Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-256-compounding-animal-drugs-bulk-drug-substances

**AVMA**

- Core Principles of Antimicrobial Stewardship: https://www.avma.org/sites/default/files/2020-10/AntimicrobialResistanceReport-StewardshipBranded.pdf
- Antimicrobial Resistant Pathogens Affecting Animal Health in the United States: https://www.avma.org/sites/default/files/2020-10/AntimicrobialResistanceFullReport.pdf
- AMDUCA Algorithm: https://www.aasv.org/documents/extralabel_brochure.pdf

**FARAD**

- http://www.farad.org/

Approved by the AASRP Board of Directors October 2020

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