Policy Statement Concerning Prudent Drug Use Guidelines

The American Association of Small Ruminant Practitioners is committed to improving the health and welfare of sheep, goats, cervids and camelids. The first three of these species are considered food producing animals by the United States Food and Drug Administration's Center for Veterinary Medicine (FDA-CVM). The principles of prudent drug use in small ruminants are the same as other food animal's species. It should be understood that the small ruminant owner's intent for the use of the animal(s) for instance, has no bearing on drug use decisions. All sheep, goats and cervids are considered food producing animals and are subject to the same legalities and constraints as other food animal species.

With the very short list of drugs and associated approved indications, the small ruminant practitioner is often forced to use drugs approved for other species in an extra-label manner. The Animal Medicinal Drug Use Clarification Act (AMDUCA) allows this, but only under certain conditions. All food animal veterinary practitioners should know the rules of AMDUCA. If the veterinarian, in his clinical judgment, does not think the labeled drug will work, or there is no labeled drug for a given indication, a different drug approved for that species should be selected first. If an appropriate choice is not available, drugs approved for other food animal species must be selected. Drugs approved for non-food animals, and then those approved for humans should be used only as a last resort. The veterinarian must remember that under AMDUCA, factors such as lower cost and convenience (long-acting formulations, oral tablets, small volumes, good syringability, availability, etc.) are not justifications for use of drugs in an extra-label manner.

The following prudent use guidelines are intended to help small ruminant practitioners select drugs appropriately while avoiding violative residues in food.

- Preventive strategies, such as appropriate nutrition, immunization and deworming programs, and biosecurity should be emphasized. This will reduce the incidence of disease and the need for drug therapy.
- Other therapeutic options (fluid therapy, physical therapy, local therapy, etc.) and culling should be considered prior to the use of systemic drug therapy.
- Drug therapy should be used only under within the confines of a valid veterinarian-client-patient relationship.
- Drug therapy regimens should be optimized using current pharmacological information and principles. Published regimens for small animals or cattle may not be appropriate for small ruminants. Practitioners should avail themselves of continuing education opportunities and species groups in order to keep current with species-specific recommendations.
- Quantities of drugs prescribed and dispensed should be appropriate, to avoid accumulation and potential misuse of drugs on the farm.
- Accurate records of treatment and outcome should be used to document and evaluate therapeutic regimens.
- Extra-label drug usage (ELDU) should be within the confines of the rules of AMDUCA.
    - ELDU includes a change in route, dosage, duration, frequency, indication or species from what is published on the label or package insert.
    - ELDU is permitted only by or under the supervision of a veterinarian.
    - ELDU is allowed only for FDA approved animal and human drugs.
    - ELDU is not permitted if it results in a violative food residue which may present a risk to public health. Practitioners should not use drugs in an extra-label manner unless

adequate scientific information is available to determine a withdrawal time. For recommendations on meat and milk withdrawal times go to www.FARAD.org

- ELDU of some drugs is prohibited. The veterinarian should have timely knowledge of this list at all times. For updates go to www.FARAD.org (list revised January 17, 2008)
  - Chloramphenicol
  - Clenbuterol
  - Diethylstilbestrol (DES)
  - Dipyrone
  - Nitroimidazoles (including dimetridazole, metronidazole and ipronidazole)
  - Nitrofurans (including nitrofurazone, furazolidone, topical use prohibited as well)
  - Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine
  - Fluoroquinolones (examples enrofloxacin and danofloxacin)
  - Glycopeptides (example vancomycin)
  - Phenylbutazone in female dairy cattle 20 months of age or older
  - Gentian Violet

(The Pasteurized Milk Ordinance (PMO) prohibits the presence of dimethyl sulfoxide (DMSO) and colloidal silver on dairies.)

- ELDU is limited to cases in which the health of the animal is threatened (ie. suffering or death may result from lack of treatment). Extra-label drug use in not permitted to enhance production.
- ELDU of medicated feed is prohibited. However, the FDA Compliance Policy Guide on Extra-label Use of Medicated Feeds for Minor Species allows this under certain conditions, including but not limited to:
  - The health of the animal is threatened.
  - The medicated feed is approved for a major food-producing species.
  - The medicated feed is formulated and labeled according to its approved labeling.
  - Other tenets of AMDUCA (valid veterinarian-client-patient relationship, proper record keeping, establishment of a suitable withdrawal period, etc.) still apply.
- The use of drugs compounded from bulk pharmaceutical ingredients in food animals is prohibited. A few exceptions to this exist and can be found in the FDA's Compliance Policy Guide on Compounding of Drugs for Use in Animals.

Helpful links: http://www.farad.org

http://www.fda.gov/cvm/MumsDesigList.htm

http://www.fda.gov/cvm/minortoc.htm

http://www.fda.gov/cvm/greenbook.html

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