FACTSHEET:
Extra Label Drug Use in Goat Production

Background

In Ontario, veterinarians have the ability to prescribe animal health products for extra-label or off-label use. This provides Ontario veterinarians with the ability to prescribe the best possible product for disease treatment, even if that product does not have a label claim for the intended species or use. This ability is critical to livestock producers, particularly in the goat sector, where goat producers do not have access to labeled products for goat production. This Extra Label Drug Use (ELDU) has provided the goat industry with treatment options that otherwise would not be available.

Relative to other livestock production, goat production is a small industry in Canada. In order for a pharmaceutical company to achieve a label claim for a product, it needs to perform thousands of dollars of research to collect enough information for the label claim to be approved. With an industry as small as the goat sector, this is not economically feasible because the returns would not be great enough to offset the costs of obtaining the label claim.

The other issue prohibiting pharmaceutical companies from pursuing label claims is that the majority of feed additives used in the goat industry have been around for so long that the patents have expired, leaving the majority of products generic. This raises the question of who would then pay for the label claim. The lack of label claims creates a very big problem in the goat industry and severely limits the products that can be safely used in goat production.

Extra Label Drug Use

ELDU is permitted in Canada under certain conditions but it is not permitted in Europe or the United States. When a veterinarian prescribes a product for extra-label or off-label use, the ELDU refers to the use or intended use of a drug approved by Health Canada in an animal in a manner not in accordance with the label or package insert. It also includes the use of all unapproved drugs, including unapproved bulk active pharmaceutical ingredients (APIs) and compounded drugs (Health Canada).

Prescribing products for extra-label use is a very delicate issue. ELDU is only permitted when there is veterinary supervision, no approved alternate product with the same efficacy exists and a valid Veterinary-Client-Patient-Relationship (VCPR) and prescription are available. Along with use in a species not specified on the label, the following examples are also considered ELDU:

- Administering the drug at a dose or frequency other than that on the label.
- Administration of the drug through a different route than that stated on the label.
- Use of the drug in a different form of feed carrier.
- Use of the drug for a purpose other than that is stated on the label (i.e. treatment of a different condition).
- Use of the drug in an animal at a different age or stage of production than that stated on the label.

Extra-label use of animal health products could potentially lead to the development of antimicrobial resistance if the correct dosage is not administered, as well as drug residues in the treated animals if the proper withdrawal time is not respected. It is also important to note that when using extra-label products there must be zero meat residues at the time of slaughter.

Regulations

The Canadian Food and Drug Regulations and the *Canadian Meat Inspection Act* state that no person may sell a product that has been “adulterated”. Adulterated means to corrupt, debase, or make impure by the addition of a foreign or inferior substance or element. An example of selling an adulterated product would be shipping a goat or milk from a goat recently receiving medication, whether it is a feed additive, water-soluble product or injectable, and that has not respected the withdrawal period.

Residues

An animal or animal product is to be free of harmful chemical residues. A residue is deemed violative if it exceeds the Maximum Residue Limit (MRL) set by Health Canada for that product and for that species and class of animal.

Maximum Residue Limit (MRL)
A MRL is a level of residue that could safely remain in the tissue or food product derived from a food-producing animal that has been treated with a veterinary drug. This residue is considered to pose no adverse health effects if ingested daily by humans over a lifetime. However, when a product is used in an extra label manner, Health Canada and the Canadian Food Inspection Agency has established a zero tolerance regardless of any other factor.

Veterinarian-Client-Patient-Relationship (VCPR)
As a goat producer, it is your responsibility to have an ongoing relationship with a veterinarian. To maintain that relationship, the veterinarian must do a farm visit at least yearly. It is also your responsibility to have prescriptions for all animal health products being used on-farm, including feed additives and over the counter (OTC) products if they are used extra label. It is also your responsibility to understand what the prescription is for and to have a clear understanding of and respect the meat or milk withdrawal.

If you currently do not work with a veterinarian and you are using extra-label products including feed additives, it is recommended that you consult with a veterinarian who has experience in the goat industry to obtain the proper prescriptions. ELDU is only permitted in Canada under veterinary supervision and with a valid VCPR and updated prescription.

The Canadian Global Food Animal Residue Avoidance Databank
The Canadian Global Food Animal Residue Avoidance Databank (CgFARAD) is a database established at the Western College of Veterinary Medicine and the Ontario Veterinary College to provide information on residue avoidance for use by veterinarians. A producer's veterinarian can contact CgFARAD and request a withdrawal recommendation from them based on the proposed prescription. If CgFARAD has data available, they are able to make a recommendation on a withdrawal time, and their recommendation has been followed, the Canadian Food Inspection Agency (CFIA) will consider the product in compliance, pending any evidence to the contrary. It is recommended that your veterinarian contact CgFARAD prior to prescribing any extra label medication for your goats.

Drug Identification Number (DIN)
A Drug Identification Number (DIN) is a computer-generated eight-digit number assigned by Health Canada to a drug product prior to being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada.

A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration.

A DIN is assigned to all authorized prescription and over-the-counter drugs. All products classified as a drug, even over-the-counter products, must be sold with a DIN. If the product is sold without a DIN, it does not comply with Canadian law and regulatory action will be taken (Health Canada).

Summary
Production of food producing animals is changing, regardless of the type of livestock you raise. Ontario Goat is working diligently on this very important issue for the goat industry. Working with your veterinarian to develop animal health protocols on your farm is critical to the success of your goat operation. Using products that have DINs and adhering to the proper meat and milk withdrawals are all part of being a responsible goat producer.

For further information, please contact:
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