

EXTRA LABEL DRUG USE IN FOOD ANIMALS

FACT SHEET



Introduction

Livestock and poultry producers take pride in using good management practices to produce safe and high quality meat, milk, eggs, and other animal products. Part of good management practice is giving appropriate and timely treatment to sick animals when necessary. If drugs are to be administered, it should be according to what it is indicated on the label.

However, there are situations when veterinary drugs are used in a manner not indicated on the label. This is commonly called **Off-label** or **Extra Label Drug Use (ELDU)**.

ELDU in Food –Producing Animal



Extra label drug use is the application of a drug product in a manner that is not exactly as indicated on the label. The information on the package insert (“label”) of any drug product approved by Health

Canada⁽¹⁾ has undergone vigorous scientific review to assure safety and efficacy. The product may also be efficacious and safe for treating other conditions where data has not yet been provided to Health Canada for label consideration.

It is legal for veterinarians to prescribe, using a written prescription, off-label use of drugs and assume full accountability because they are in the best position to critically evaluate the risks, efficacy and safety.

Potential Risks in Off-label Drugs

ELDU is a concern for public health and food safety reasons⁽²⁾:

- Harmful drug residues may be present in food products from off-label treated animals.
- Anti-microbial resistance may develop.
- Adverse reactions may occur in treated animals.
- Drug may have reduced or uncertain efficacy for the conditions being treated.

Forms of ELDU

Drug use is considered Off-label when a: ⁽¹⁾ ...

- different dosage than what is approved on the label
- greater or lesser frequency of administration than what is approved on the label
- different disease or condition than what is stated on the label
- longer or shorter duration of treatment than what is indicated on the label
- different route of administration
- different species than what is indicated on the label
- different age group
- different stage of the animal’s production cycle
- different dosage form
- approved drugs in humans to treat animals
- medicated feed not listed in the Medicated Ingredient Brochure (MIB)
- different formulation

ELDU Practice in Canada

Health Canada, through the Veterinary Drug Directorate (VDD), approves the drugs for sale in Canada. To sell livestock medicine, the manufacturer must prove that these drugs⁽³⁾:

- are safe for the animals
- are effective when the recommended dosage is used for the species identified.
- will not have residues that affect humans as they consume foods derived from animals
- are manufactured according to strict specifications and remain stable up to the expiry date

A drug licensed to treat pneumonia in calves must not harm the calf and the manufacturer must prove that calves with pneumonia treated with the drug have a better chance of survival than calves that are not treated.

The approval of veterinary drugs is very costly. It requires an intensive series of toxicity and pharmacologic tests (does no harm). New drug licensing is a very expensive proposition for pharmaceutical companies. Therefore, there is a relatively short list of available veterinary drugs on the market. Pharmaceutical companies are reluctant to test drugs in species that are considered minor in terms of economic value as there is no return on investment.

The practice of veterinary medicine and the sale and distribution of approved drugs are within provincial authority. Veterinarians in Canada are allowed to use drugs in species in which the drug has not been licensed if there is a reasonable scientific basis for their use.

In livestock production, flunixin meglumine and penicillin are most frequently employed for extra-label use. Both drugs are used to treat dairy cattle. Flunixin meglumine is a non-steroidal anti-inflammatory drug (NSAID). In 1990, this drug was indicated solely for equine use in Canada; in 2003, however, flunixin meglumine received approval for use in cattle. The extra-label use of penicillin involved the application of a higher dosage than the label indication ⁽¹⁾

In Canada there are very few products that are licensed for use in small ruminants, sheep goats and llamas. An identical chemical may be available for cattle and licensed for use in other countries such as Australia, which has a large small ruminant economy.

ELDU is legal practice in veterinary medicine for proper and humane care of sick animals. Countries including the United States, the European Union, Australia, and New Zealand control off-label use by the requirement of a prescription from a licensed veterinarian.

Guiding Principle on ELDU



The Canadian Veterinary Medical Association (CVMA), various associations of food producing animals and feed companies have one unified position. Conditions for the use of ELDU in livestock treatment include ⁽⁴⁾:

- strict requirement for prescription from licensed veterinarian
- a valid Veterinarian-Client-Patient relationship (VCPR)
- conformity with the *Food and Drugs Act & Regulations*
- non-usage of antimicrobial drugs having very high importance to humans

Conclusion

Responsible veterinarians, especially those treating small ruminants, are frequently required to use veterinary drugs in a manner that is not in accordance with the Canadian-approved label directions. It is acceptable for veterinarians to use drugs in an extra label manner in the following conditions:

- to alleviate the pain and suffering of individual animal
- in cases of severe life-threatening disease
- when no approved/ licensed drug is available to treat the condition
- in the veterinarians' professional opinion it is likely that the drug treatment regime will be safe and efficacious.

Responsible and judicious use of livestock medicines is necessary to assure animal welfare and safety of Canada's food supply.

References

1. http://www.hc-sc.gc.ca/dhp-mps/pubs/vet/eldu-umdde_issue-enjeux_final_10-12-2004-eng.php#1.7
2. http://www.hc-sc.gc.ca/dhp-mps/vet/faq/facts-faits_animals_eldu-umde-eng.php
3. http://www.hc-sc.gc.ca/dhp-mps/vet/faq/faq_dap-pam-eng.php
4. http://www.hc-sc.gc.ca/dhp-mps/vet/label-etiquet/pol_eldu-umdde-eng.php

For further information please refer to the Office of the Chief Veterinarian [Contact List](#) at: manitoba.ca/agriculture/foodsafety