Canadian Veterinary Medical Association

Association canadienne des médecins vétérinaires

Extra-Label Drug Use (ELDU) in Veterinary Medicine

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Position

The Canadian Veterinary Medical Association (CVMA) holds that Extra Label Drug Use (ELDU) is an important and legally-acceptable strategy for the effective treatment of animals only by a licensed veterinarian within the confines of a valid veterinary-client-patient relationship (VCPR) and only in circumstances where an approved veterinary product or drug is not available or is not suitable.

Summary

- ELDU in animals should only be considered by the prescribing veterinarian within the confines of a valid veterinary-client-patient relationship in accordance with policies and guidelines of the responsible regulatory authority when supported by proper documentation and supporting evidence, sound reasoning and in accordance with a documented decision cascade.
- Veterinarians should consult the CgFARAD for residue avoidance information, as needed.
- ELDU should be considered within the context of antimicrobial stewardship which aims to minimize the emergence and spread of antimicrobial resistance.
- Veterinarians must not use drugs (including ELDU) in food animals that are prohibited for use in such animals (13).

Background

1. In veterinary medicine ELDU (often referred to as “off-label use”) is defined as the use in animals of:
    - A prescription or over-the-counter (OTC) pharmaceutical product in a manner that is not in accordance with Health Canada’s approved label or the Compendium of Medicating Ingredients Brochure published by the Canadian Food Inspection Agency (1,2).
    - Any approved drug that is administered in a manner not explicitly stated on the approved label with regard to indication, dosage regimen, route or frequency of administration, duration of treatment, or target species (1,2).
    - Any drug approved for human use but not veterinary use (3).
    - Compounded drugs (including compounded Active Pharmaceutical Ingredients (APIs)) (4,5).

2. Veterinarians play a pivotal role in the health and welfare of animals and have the professional training, experience, continuing education, and regulatory knowledge to best counsel clients on the requirements and responsibilities associated with ELDU (6).
3. Veterinarians are often faced with cases for which approved drugs are not available for the disease encountered and/or for the complete range of animal species requiring therapy, or in which the label instructions for dosage regimen or frequency of administration have proved to be ineffective.
4. ELDU in animals should only be considered by the veterinarian within the confines of a valid veterinary-client-patient relationship (VCPR) where there is evidence to support efficacy and the dosage regimen for the disease, and in the species being treated. The circumstances for the use of ELDU must be in accordance with the provincial or territorial veterinary regulatory authority's policy or guidelines. A decision tool such as the CVMA therapeutic decision cascade is a useful model to follow with respect to ELDU (7).
5. The CVMA supports efforts by Health Canada and the pharmaceutical industry to approve more drugs for minor/less common (food animal and non-food) animal species.
6. When prescribing ELDU for food-producing animals, veterinarians should provide owners/producers with the appropriate information on dosage regimen, route and frequency of administration, duration of treatment, and withdrawal interval to avoid a risk to food safety from potential drug residues. Veterinarians should document the extra-label use of drugs and that they obtain the "informed consent" of the owner/producer after any risks have been explained.
7. It is recommended that veterinarians consult with the CgFARAD for residue avoidance information when prescribing a product with a Drug Identification Number (DIN) ELDU to a food-producing animal (8). Use of a compounded product (either a DIN Drug or API) in an animal intended for food may result in a "hold and test" situation at slaughter to confirm freedom from violative residues.
8. In Canada, the use of medically important antimicrobials (MIA) in animals can only occur pursuant to a veterinary prescription under a valid VCPR (9,10). Some MIA prescribed by veterinarians are essential for the treatment of serious life-threatening infections in humans (Veterinary Drug Directorate Category I (Very High Importance in Human Health) antimicrobials) (11). Decisions pertaining to ELDU of MIAs in animals should always be with careful consideration to the principles of antimicrobial stewardship (10).
9. As stated in the 2016 document *Veterinary Oversight of Antimicrobial Use – A Pan-Canadian Framework of Professional Standards for Veterinarians* produced by the CVMA and Canadian Council of Veterinary Registrars "Drugs or classes of Very High Importance in human medicine which are listed as Class I Antimicrobials by Health Canada should not be used in an extra-label manner in animals destined for the food chain and should only be used in other animals if all alternatives have been exhausted, there is culture and sensitivity supporting their use, and the animal is determined to have a reasonable chance of survival." (12).
10. Veterinarians must not use drugs (including ELDU) in food animals that are prohibited for use in such animals (13).

References

1. Health Canada. Policy of Extra-Label Drug Use (ELDU) in Food-producing Animals. Available from: **https://www.canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs/extra-label-drug-use/policy-extra-label-drug-use-eldu-food-producing-animals.html** Last accessed January, 2021.
2. Health Canada. Extra-Label Drug Use in Animals. Available from: **https://www.canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs/extra-label-drug-use.html** Last accessed January, 2021
3. Health Canada. Veterinary Drugs. Available from: **https://www.canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs.html** Last accessed January, 2021.
4. Health Canada. Oversight on the Quality of Active Pharmaceutical Ingredients for Veterinary Use in Canada. Available from: **https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/oversight-quality-active-pharmaceutical-ingredients-veterinary-use.html** Last accessed January, 2021.
5. Canadian Veterinary Medical Association Guidelines for the Legitimate Use of Compounded Drugs in Veterinary Practice (2006). Available to CVMA members only from: **http://www.canadianveterinarians.net/documents/cvma-guidelines-for-legitimate-use-of-compounded-drugs-in-veterinary-practice-2006** Last accessed January, 2021.

6. CVMA Guidelines for Veterinary Antimicrobial Use. Available to Canadian veterinarians from: **https://www.canadianveterinarians.net/AMU-UAM** . Last accessed January, 2021.
7. Canadian Veterinary Medical Association. Therapeutic Decision Cascade for Animal and Public Safety. Available from: **https://www.canadianveterinarians.net/documents/therapeutic-decision-cascade**. Last accessed January 2021.
8. CgFARAD. Available from: **https://cgfarad.usask.ca/language.php** Last accessed January, 2021.
9. Health Canada. Responsible Use of Medically Important Antimicrobials in Animals. Available from: **https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/actions/responsible-use-antimicrobials.html** Last accessed January, 2021.
10. CVMA. Antimicrobial Stewardship in Veterinary Medicine (Position Statement) (2021). Available from: **https://www.canadianveterinarians.net/documents/antimicrobial-stewardship-in-veterinary-medicin**e. Last accessed June 2021.
11. Health Canada. Categorization of Antimicrobial Drugs Based on Importance in Human Medicine (2009). Available from: **https://www.canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs/antimicrobial-resistance/categorization-antimicrobial-drugs-based-importance-human-medicine.html** Last accessed January, 2021.
12. Veterinary Oversight of Antimicrobial Use – A Pan-Canadian Framework of Professional Standards For Veterinarians. Available from: (**https://www.canadianveterinarians.net/policy-advocacy/framework**). Last accessed January, 2021.
13. Health Canada, Veterinary Drugs Directorate (VDD) . List of Banned Drugs. Available from: **https://www.canada.ca/en/health-canada/services/drugs-health-products/veterinary-drugs/list-banned-drugs.html** Last accessed January, 2021.

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