



## POSITION STATEMENT

### CAHI SUPPORTS THE COMPOUNDING AND DISPENSING OF ANIMAL HEALTH PRODUCTS ONLY WHEN A SUITABLE LICENSED PRODUCT IS UNAVAILABLE

August 21, 2018

**Compounding** is a practice that may be necessary for the treatment of animals because it allows veterinarians to provide **animal health products** in a dose or form that is otherwise unavailable. Veterinarians use compounding to give medication to animals that are hard to treat (e.g. because a pet will not swallow a pill), because more than one drug would have to be given at a time (e.g. cancer treatments), because the usual form of the drug is not easy to use for the species (e.g. licensed drug for cattle but needs to be given to fish) or because the correct dose is not available for the size of the patient (e.g. licensed drug is for chickens but needs to be given to sheep).

**CAHI is supportive of the legitimate compounding and dispensing, by licensed veterinarians and pharmacists, of animal health products not available in the needed dosage form for the treatment of individual patients, within the confines of a veterinarian-client-patient relationship.**

Changing how a medication is given means there are increased risks because it may involve the use of raw chemicals, or the alteration of the form and strength of a product as licensed by Health Canada. Licensed drugs have been assessed for safety, efficacy and effectiveness by Health Canada's scientists and must meet the requirements of the [Food and Drugs Act](#) and its [Regulations](#). These assessments do not apply to compounded medications and prescribing them is considered **Extra-Label Drug Use**.

For compounded products, the prescribing veterinarian is responsible for the safety and efficacy of the product and for establishing **withdrawal times** if the patient is a food animal. Animal medications can only be prescribed for patients if there is a valid **veterinarian-client-patient relationship** in place. Because of the risks involved, compounding is activity falling under the provincial legislation that governs the scope of activities for pharmacists and veterinarians.

Risks associated with compounded products:

- No assurance that the raw materials are pure and potent, or that manufacturing followed best practices
- No stability testing of the product or expiry date
- No stability or **pharmacokinetics** information is available for one or more of the ingredients
- Withdrawal times or **maximum residue limits** may not have been established for one or more of the ingredients
- No technical support to the veterinarian or pharmacist from the product manufacturer
- Increased liability to the prescribing veterinarian and/or the dispensing pharmacist

.../2

Compounding is not to be used to:

- Bypass Health Canada's drug review system
- Create counterfeit products identical to licensed animal health products
- Manufacture bulk quantities of animal health product for sale outside of the veterinarian-client-patient relationship
- Provide a compounded product that is equivalent to a licensed product at a lower price

CAHI is also supportive of the [Canadian Veterinary Medical Association's Decision Cascade](#). When veterinarians find compounding is needed to treat a patient, the highest possible level on this cascade should be applied.

#### **GLOSSARY:**

**Animal Health Products** include pharmaceuticals, vaccines, and feed additives and are used to keep animals healthy and productive. They include medicines like anti-inflammatories, anesthetics, biologicals, pesticides and antibiotics. They may be given to an animal by mouth (e.g. feed, water), injection or topically.

**Compounding** is the mixing of two or more ingredients, and at least one of these is a drug or other pharmacologically active chemical, to create a final product in a form that is more appropriate for the patient in terms of dose, acceptability or ease of use. More information about compounding can be found on Health Canada's [website](#).

[Extra Label Drug Use](#), also referred to as "off-label use", 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.

[Maximum residue limits](#) are established by Health Canada, based on scientific data and international guidelines, and are the amount of residue(s) that could remain in the meat, milk or eggs from a food animal that has been treated with a drug. This level of residue is considered to pose no adverse health effects if ingested daily by humans over a lifetime.

**Pharmacokinetics** is the study of how a drug will move into, through and out the body, and includes the amount available in the body to be effective as well as how it is absorbed, metabolized, and excreted.

A [veterinary-client-patient-relationship](#) is the relationship between the veterinarian and the client and their animals. The precise definition of this relationship varies by province across Canada; however, this relationship can usually be documented.

**Withdrawal time** is the time needed after a drug is given to a food animal to ensure that it has moved through the body and will no longer be present, or present below the maximum residue limit in meat, milk and eggs.