



POSITION STATEMENT

CAHI SUPPORTS CANADIAN RESTRICTIONS ON OUI FOR VETERINARY DRUGS

August 27, 2018

A veterinary drug is approved and licensed by Health Canada's Veterinary Drugs Directorate for the claims that appear on the label. When a drug is approved a Drug Identification Number (DIN) is issued and this must appear on the label. Due to needs in human medicine, Own Use Importation (OUI) of a three (3) month supply of a finished drug product for personal use is permitted by Health Canada as long as the importing person has no intention of selling the product. This policy does apply to animals as well; however, controls have been put in place to ensure that it is not used to by-pass the Canadian animal health product review process.

- As of November 13, 2017 [medically important antimicrobials \(categories I, II and III\)](#) can no longer be imported for own use by animal owners. Details of this regulatory change are available through the [Veterinary Drugs Directorate at Health Canada](#).
- Health Canada has developed the [List B: List of certain veterinary drugs which may be imported but not sold](#) for those animal health products that can be imported into Canada for own use.

CAHI is committed to healthy animals, a safe food supply and a robust and timely review of all animal health products and it applauds the new OUI regulatory changes put in place by Health Canada in 2017. According to the HealthforAnimals [2015 Global Benchmarking Survey Benchmarking the competitiveness of the global animal health industry: Canada Report](#), OUI accounted for up to 20% of the opportunity value of licensed product or a potential loss in sales of \$150 million. There are also a number of concerns surrounding the use of unapproved product that animal owners should be aware of. These include:

- Products without a DIN are not approved or regulated by Health Canada, meaning data regarding their purity, safety, stability, and efficacy may not be known.
- A foreign licensed veterinary drug may not meet Canadian standards for safety, efficacy and quality. Withdrawal times may be different for the Canadian licensed product from that of the foreign licensed product.
- Importation of unapproved products has the potential to compromise food safety, international trade and consumer confidence in the food supply.
- Should adverse reactions occur as a result of the use of an imported product, the manufacturers of products imported into Canada are not required to provide technical support or compensation.

Did you know?

Importers of veterinary biologics must obtain an [import permit](#) from the Canadian Centre for Veterinary Biologics of the Canadian Food Inspection Agency to import veterinary biologics.