



## *Veterinary Oversight of Antimicrobial Use*

Published November 2017

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### **Importing medically important antibiotics for use in food animals ends November 13, 2017**

The Government of Canada through Health Canada is restricting personal importation (also known as own use importation) of veterinary drugs for food-producing animals or animals intended to be consumed as food (including horses).

The restrictions on importation for personal use will begin when the regulations come into effect on **November 13, 2017**. This means no Medically Important Antimicrobials will be authorized for importation after that date.

Visit <https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/personal-importation-certain-drugs-food-producing-animals.html> to find out more details:

- Changes to the rules
- Who these rules apply to
- Criteria for adding a drug to List B
- How to request a drug be added to List B
- How to import a drug for food-producing animals
- Food safety and comparable Canadian drugs

### **Medically important antimicrobials for veterinary use will be sold by prescription only as of December 1, 2018**

Health Canada is moving a number of Medically Important Antimicrobials (MIAs) approved for veterinary use before 2004 to the Prescription Drug List (PDL). With this change, Health Canada will establish the same level of oversight for those MIAs approved before 2004 as for those approved after.

As of **December 1, 2018**, all MIAs for veterinary use will be on the PDL and must be sold by prescription only.

## Timelines for the changes

- Until December 1, 2018, the drugs listed in the '[Prescription status – affected drugs and dosage forms](#)' section will **not** be prescription status.
- As of December 1, 2018, the drugs listed in the '[Prescription status – affected drugs and dosage forms](#)' section **will** be prescription status.
- Beginning early 2018, you may start to see some label changes on the market during the transition between old and new labels.
- Read more: <https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/actions/responsible-use-antimicrobials.html>

## Acknowledgement

Adapted with permission from the CVMA's October 10, 2017 and October 18, 2017 publications.



# Health Canada is strengthening Canada's regulatory framework for veterinary antimicrobials

May 2017

Regulation changes published Canada Gazette Part II

November 13, 2017

### Regulations Coming Into Force: OUI, VHPs

**OUI:** MIAs used in food-producing animals may no longer be imported into Canada under the OUI Policy. Going forward, only drugs that Health Canada has determined do not pose a risk to human health or food safety may be imported – and only in limited quantities. Refer to the exempted product list established by Health Canada: *List B: List of Certain Veterinary Drugs Which May Be Imported But Not Sold*

**VHP:** A flexible, risk based regulatory framework allowing companies to import and sell products for food and companion animals. These products are intended to promote the health and welfare in animals.

May 17, 2018

### Coming into force APIs, GMPs, DELs\*

Expansion of GMP regulatory requirements for human APIs to veterinary APIs.

Expands existing regulatory requirements to manufacture according to GMPs for APIs for human drugs to all veterinary APIs.

Pharmacists, veterinarians or those compounding a drug under the supervision of a licensed veterinarian must hold a DEL when importing MIAs that are on Incorporated by Reference list – *List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients*. The importation of MIA APIs by food animal producers for their direct use in food animals will not be allowed.

\* Additional 14-month transition period ending July 17, 2019 to submit a DEL application.

January 1, 2019

### Mandatory reporting of sales volume

As of January 1, 2018, reporting of sales information will no longer be voluntary for manufacturers, importers and compounders.

The 2018 data must be submitted to Health Canada between January 1, 2019 and March 31, 2019.

December 2017

### Notice of Intent to amend PDL

Health Canada advises stakeholders of plans to include all MIAs on the PDL which will require their sale to be done pursuant to a prescription (this includes in-feed).

This change was consulted on during the summer of 2017 and will be enforced as of Dec. 1, 2018

February 2018

### VDD approval of labels

Revised labels approved by Health Canada:

- Pr status
- Removal of growth promotion claims

April 2018

### Update of CMIB

New CMIB look and feel  
All approved in-feed drugs (including OTC and Pr) to be included in CFIA's CMIB

December 1, 2018

### Updated PDL published

All MIAs for Veterinary Use will be Sold by Prescription Only.

### Regulatory Changes Policy Changes

**Acronyms:**  
 API – Active Pharmaceutical Products  
 CFIA – Canadian Food Inspection Agency  
 CMIB – Compendium of Medicating Ingredient Brochures  
 DEL – Drug Establishment License  
 GMP – Good Manufacturing Practice  
 MIAs – Medically Important Antimicrobials  
 OUI – Own-Use-Importation  
 PDL – Prescription Drug List  
 VDD – Veterinary Drugs Directorate  
 VHP – Veterinary Health Product  
 Pr – Prescription  
 OTC – Over the Counter

### Marketplace adjustment and transition

- Inventory management at retail level
- Outreach to all stakeholders



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