CANADIAN VETERINARY MEDICAL ASSOCIATION
L'ASSOCIATION CANADIENNE DES MÉDECINS VÉTÉRINAIRES

# Health Canada is strengthening Canada's stewardship of veterinary antimicrobials

CONTAINS ANTIMICROBIAL USE RESPONSIBLY

## 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.

**Marketplace adjustment and transition:**
- **Inventory management at retail level**
- **Outreach to all stakeholders**

**Acronyms**:
API – Active Pharmaceutical Ingredients
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 (personal use)
PDL= Prescription Drug List
VDD = Veterinary Drugs Directorate, Health Canada
VHP = Veterinary Health Product
Pr = Prescription
OTC = Over the Counter

**Regulatory Changes**

**Policy Changes**