

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 Health Canada's GMP regulatory requirements for human APIs to veterinary APIs.

Expands existing Health Canada 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

HC approval of labels

Revised labels approved by Health Canada:

- Pr status
- Removal of growth promotion claims

April 2018

Update of CFIA's 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 approved by Health Canada will be Sold by Prescription Only.

**Regulatory Changes
Policy Changes**

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

