# Guidance for Pharmacists on Veterinary Use Medications

To ensure that antimicrobial drugs maintain their effectiveness and to reduce the spread of antimicrobial resistance, Health Canada has introduced legislation enforcing the responsible use of Medically Important Antimicrobials (MIAs) in veterinary medications.

## Legislation Changes

On May 17, 2018, new legislation for Active Pharmaceutical Ingredient (API) for veterinary use came into effect. This legislation was introduced to increase oversight on importation and quality of API for veterinary use. These include changes to require manufacturing according to good manufacturing practices (GMP), to require a drug establishment licence (DEL) to manufacture, import, package, label and test API for veterinary use and to require a DEL for pharmacists and veterinarians to import API on List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients. The regulatory changes also increase oversight on importation of veterinary drugs by restricting the personal importation (also known as own use importation) of drugs for food-producing animals to those on List B: List of Certain Veterinary Drugs Which May be Imported But Not Sold. List B is a regulatory list of veterinary drugs for food-producing animals allowed to be imported for personal use. This change came into effect on November 13, 2017.

Further to these changes, Health Canada has made sales reporting mandatory in an effort to increase antimicrobial surveillance. Annual submission of sales reports of MIAs for veterinary use on List A must be submitted to Health Canada by manufacturers, importers and compounders of these products. Sales reporting will begin for the year of 2018 (January to December) and information must be submitted by March 31 of each year therefore the first required submissions to Health Canada will be March 31, 2019, for sales in 2018.

On December 1, 2018, Health Canada will be enforcing new legislation that ensures all Medically Important Antimicrobials will be sold by prescription only. This means that a valid prescription will be needed from a veterinarian for a prescription medication or prescription medicated feed in order to be sold. There will also be changes made to the labels of MIAs that manufacturers must comply with such as:

- removing growth promotion claims and related directions for use
- addition of responsible use statements on labels of all in-feed and in-water MIAs
- addition of a “Pr” on the principal display panel to show that it is a prescription drug

**DIN Drug premix:** a drug for veterinary use to which a drug identification number (DIN) has been assigned, where the directions on its label specify that it is to be mixed with feed.

## Sale by Pharmacists

Pharmacists can sell a prescription drug to animal owners/end users such as food-animal producers with on-farm feed mills and companion animal owners who provide a prescription. Pharmacists can sell the following with a valid prescription from a veterinarian:

**Prescription medications**: injectables, in-water and in-feed formulations.

**Prescription medicated feeds**: livestock feed that contains a prescription drug such as supplements, macro and micro premixes and complete feed

Pharmacists **cannot** sell a prescription drug to a retail store such as livestock medicine outlets, farm supply stores or feed stores.

## Purchase by Pharmacists

Pharmacists can purchase prescription drugs (including a DIN drug premix) from drug companies that hold a DEL from Health Canada and comply with GMP.

Pharmacists can also purchase DIN drug premixes in the form of whole bags from commercial feed mills who have demonstrated compliance with drug GMPs from Health Canada.

## Sales Reporting

Sales reporting of veterinary antimicrobials has become mandatory by Health Canada to better understand the volume of antimicrobials available for use in animals. Health Canada will use this information to assess trends of antimicrobial resistance and to assess the impact that antimicrobial use in animals has on human health. Sales reporting will be mandatory for all manufactures, importers and compounders of MIAs for veterinary use and are required to be submitted yearly to Health Canada by March 31 of each year. Sales reports of drugs on List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients for veterinary use must include the following:

- the total quantity sold or compounded
- the approximate quantity sold or compounded for each intended animal species.

Pharmacists who compound these products will be able to access the sales reporting form at the bottom of the Health Canada webpage here.

## Commercial Feed Mills

Commercial feed mill (CFM) is considered a wholesale druggist that mixes and manufactures feed for commercial sale in accordance with the *Feeds Act and Regulations*. DIN drug premixes can be sold directly to CFMs from drug companies without a prescription. The DIN drug premix is then mixed with feed ingredients to make medicated feeds which can then be sold pursuant to a prescription.

With a prescription, commercial feed mills can sell **medicated feed** containing a prescription drug to **end-users** in the form of:

- Supplement
- Micro premix
- Macro premix
- Complete feed

Commercial feed mills **cannot** sell a DIN drug premix to end users even with a prescription. End users must purchase these products pursuant to a prescription from veterinarians or pharmacists. The only way a CFM could sell a DIN drug premix would be to become a wholesaler and comply with Health Canada requirements of drug GMP.

Can commercial feed mills sell any other formulations of veterinary prescription products other than prescription DIN drug premixes or prescription medicated feeds?

No. To be able to sell injectables, implants and water-soluble prescription drugs to veterinarians or pharmacists, you must be a wholesaler, comply with drug GMPs and hold a DEL from Health Canada.

**Summary of Key Messages:**

**As of May 17, 2018**: pharmacy professionals who import Active Pharmaceutical Ingredients (API) on List A to prepare or compound drugs for veterinary use need to obtain a Drug Establishment Licence (DEL) from Health Canada.

- There is a transition period for those who were already conducting this activity.
- If a pharmacy professional was already importing API on List A for veterinary use, he/she has until July 17, 2019 to apply for a DEL
- If a pharmacy professional is new to the activity of importing API on List A for veterinary use, he/she must obtain a DEL before engaging in the activity.

**Starting with the year 2018**: pharmacy professionals who compound antimicrobial drugs for veterinary use that contain an API on List A will need to report annual sales data to Health Canada.

**Pharmacy professionals DO need to report (regulatory requirement):**

- Sales of compounds prepared using an API on List A for veterinary use
- Sales of compounds prepared using an approved drug product (DIN product) that contains an API on List A, for veterinary use

**Pharmacy professionals ARE ENCOURAGED TO report (but it is not mandatory):**

- Sales of DIN products that contain an API on List A, that are approved for human use only, but are sold off-label for veterinary use pursuant to a prescription

**Pharmacy professionals do NOT need to report:**

- Sales of DIN products that are approved for veterinary use, that contain an API on List A as is, in the Health Canada approved format, with no compounding involvement.

**Pharmacy professionals need to collect sales data from January to December 2018 and report it to Health Canada by March 31, 2019, and then annually thereafter.**

Sales reports of drugs on List A must include:

- The total quantity sold or compounded
- The approximate quantity sold or compounded for each intended animal species

**As of December 1, 2018:** all medically important antimicrobials (MIAs) for veterinary use will require a prescription.

- A prescription is required to provide medically important antimicrobials for veterinary use
- All MIAs will be on the Prescription Drug List – Products for Veterinary Use
- This will change the way pharmacy professionals can access and/or sell these drugs

## Resources

Canada Gazette II publication of regulatory changes
http://www.gazette.gc.ca/rp-pr/p2/2017/2017-05-17/html/sor-dors76-eng.html

List A: List of Certain Antimicrobial Active Pharmaceutical Ingredients.
https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/veterinary-antimicrobial-sales-reporting/list-a.html

List B: List of Certain Veterinary Drugs Which May be Imported But Not Sold
https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/personal-importation-certain-drugs-food-producing-animals/list-b.html

List C: Veterinary Health Products
https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/veterinary-health-products/list-c.html

Antimicrobial resistance and animals - Actions
https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/actions.html#a2

Establishment Licence Information
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences.html

Drug Establishment Licence Application: Forms and Instructions
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/drug-establishment-licence-application-instructions-0033.html

Veterinary Antimicrobial Sales Reporting
https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/veterinary-antimicrobial-sales-reporting.html

Responsible use of Medically Important Antimicrobials in Animals
https://www.canada.ca/en/public-health/services/antibiotic-antimicrobial-resistance/animals/actions/responsible-use-antimicrobials.html

Prescription Drug List – Products for Veterinary Use https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/prescription-drug-list/list.html#a2

For questions about drug Good Manufacturing Practices, email
GMP_Questions_BPF@hc-sc.gc.ca

For questions about Drug Establishment Licenses, email
DEL_Questions_LEPPP@hc-sc.gc.ca

Questions?
info@saskpharm.ca

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