



## FACT SHEET: ACCESSING AND SELLING PRESCRIPTION VETERINARY DRUGS

### Responsible use of Medically Important Antimicrobials

#### CONTEXT

As of December 1, 2018, all [Medically Important Antimicrobials \(MIAs\) for veterinary use](#) will be sold by prescription only. Antimicrobial drugs are important to fight bacterial infections in humans and animals. The responsible use of MIAs is intended to preserve their effectiveness and minimize the development and spread of antimicrobial resistance. **We all have a role to play.**

This fact sheet explains the federal rules on how **prescription (Pr) drugs** (in dosage form) can be accessed and sold in Canada – it does not apply to the non-prescription drug context. It is important to note that the distribution and sale of Pr drugs is a shared authority, and some provinces and/or territories may authorize certain facilities, beyond veterinary clinics and pharmacies, to sell Pr drugs, for example in Quebec where a permit regime exists. Consult your provincial/territorial authority for further details.

#### TERMINOLOGY

- **Drug premix** is defined in the *Food and Drug Regulations* [C.01A.001] – it means 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... For clarity of this Fact Sheet, the term used is “**DIN drug premix**”.
- **Wholesale druggist** does not have a regulatory definition. For clarity of this Fact Sheet, examples of wholesale druggists include wholesalers and commercial feed mills (who may access DIN drug premixes to support their operations).
- **Wholesaler** is defined in the *Food and Drug Regulations* [C.01A.001] – it means a person... who sells... a drug that is a prescription drug... other than at retail sale.
- **Commercial feed mill** does not currently have a regulatory definition. For clarity of this Fact Sheet, a commercial feed mill is considered a wholesale druggist and is a facility that mixes and manufactures feed for commercial sale in accordance with the *Feeds Act and Regulations*.
- For clarity of this Fact Sheet, **retail stores** include facilities such as livestock medicine outlets, farm supply stores or feed stores – it does not include pharmacies or veterinary clinics.
- For clarity of this Fact Sheet, in the context of veterinarians and pharmacists, **sale** includes dispensing for sale.

#### INFORMATION FOR ANIMAL OWNERS / END USERS

For animal owners/end users, including food animal producers (who may make their own feed) and companion animal owners, in order to purchase a prescription drug for your animal, you first need to obtain a prescription from your veterinarian.

With a prescription, veterinarians and pharmacists can sell you a **prescription drug** (including DIN drug premixes for mixing in feed, injectables, implants and in-water drugs).

With a prescription, commercial feed mills can sell you a **medicated feed containing a prescription drug**. It must be sold in the form of a complete feed, supplement, macro premix, or micro premix. A veterinarian is also allowed to sell you a Pr medicated feed, but most do not have facilities to produce mixed feeds in these forms.

You cannot give or sell a **Pr drug in any form** to someone else.

## INFORMATION FOR DRUG COMPANIES

Drug companies can sell a **prescription drug** (including a DIN drug premix) to:

- Other drug companies (manufacturers)
- Veterinarians
- Pharmacists
- Wholesale druggists (such as other wholesalers and commercial feed mills who may access DIN drug premixes to support their operations)

Drug companies must comply with drug good manufacturing practices (GMP) and obtain a Drug Establishment Licence (DEL) from Health Canada.

A **Pr drug** cannot be sold to a retail store (such as livestock medicine outlets, farm supply stores or feed stores) or to animal owners/end users.

## INFORMATION FOR VETERINARIANS AND PHARMACISTS

Veterinarians and pharmacists can sell a **Pr drug** (including a DIN drug premix and medicated feed) to end users (such as food-animal producers with on-farm feed mills and companion animal owners) who have a prescription.

A **Pr drug** cannot be sold to a retail store (such as livestock medicine outlets, farm supply stores or feed stores).

If you wholesale **DIN drug premixes** (for mixing in feed) or **other Pr drugs** (including injectables, implants and in-water drugs), refer to the “Information for Wholesalers” below, and note the GMP and DEL wholesale requirements.

## INFORMATION FOR COMMERCIAL FEED MILLS

The term **Commercial feed mill** does not currently have a regulatory definition. For clarity of this Fact Sheet, a commercial feed mill is considered a wholesale druggist and is a facility that mixes and manufactures feed for commercial sale in accordance with the *Feeds Act* and *Regulations*. A **DIN drug premix** (for mixing in feed) can be sold directly to you without a prescription. You can then mix the DIN drug premix with feed ingredients to make medicated feed.

With a prescription, you can sell a **Pr medicated feed** in the form of a complete feed, supplement, macro premix, or micro premix to end users (such as food-animal producers or an on-farm feed mill). These activities do not require you to comply with drug GMPs or obtain a DEL from Health Canada.

You cannot sell a **DIN drug premix** to end users (such as food-animal producers with on-farm feed mills) even with a prescription, unless you are authorized under the laws of a province or territory to do so with a prescription (for example in Quebec where a permit regime exists). If you want to wholesale **DIN drug premixes** to a veterinarian, pharmacist or another commercial feed mill or wholesaler, you need to comply with drug GMP (where products are to be stored and handled in accordance with the label), but you do not need to obtain a DEL.

If you want to wholesale **Pr drugs other than DIN drug premixes** (including injectables, implants and in-water drugs), refer to the “Information for Wholesalers” below, and note the GMP and DEL wholesale requirements.

## INFORMATION FOR WHOLESALERS

Drug companies can sell **Pr drugs** (including DIN drug premixes, injectables, implants and in-water drugs) directly to wholesalers without a prescription.

As a wholesaler, you can sell these **Pr drugs** and **DIN drug premixes** without a prescription to:

- Other drug companies (manufacturers)
- Veterinarians
- Pharmacists
- Wholesale druggists (such as other wholesalers and commercial feed mills)

If you wholesale **Pr drugs other than DIN drug premixes**, you need to comply with GMP and obtain a DEL for the activity of wholesale.

If you only wholesale **DIN drug premixes** to a veterinarian, pharmacist or another commercial feed mill or wholesaler, you need to comply with drug GMP (where products are to be stored and handled in accordance with the label), but you do not need to obtain a DEL.

A **Pr drug** cannot be sold to a retail store (such as livestock medicine outlets, farm supply stores or feed stores) or to animal owners/end users.

## INFORMATION FOR RETAIL STORES

Retail stores (such as livestock medicine outlets, farm supply stores or feed stores) cannot access or sell **Pr drugs in any form** to anyone (even with a prescription).

### FOR MORE INFORMATION

- **For questions about Veterinary prescription drugs**, email: [hc.vetdrugs-medsvet.sc@canada.ca](mailto:hc.vetdrugs-medsvet.sc@canada.ca).
- **For questions about drug GMP**, email: [GMP\\_Questions\\_BPF@hc-sc.gc.ca](mailto:GMP_Questions_BPF@hc-sc.gc.ca)
  - For more information about GMP, click [here](#).
  - For more information about preparing for a GMP wholesaler inspection, click [here](#).

To comply with expectations as a wholesaler of a Pr Drug or DIN Drug Premix you will need to understand obligations in Part C Division 2 of [Food and Drug Regulations](#). You can find more information in Health Canada's [Good manufacturing practices guide for drug products \(GUI-0001\)](#). This includes obligations related to Premises (C.02.004), Personnel (C.02.006), Manufacturing control (C.02.012), Quality control department (C.02.013 -15) and Records (C.02.021-24).

- **For questions about the [Feeds Act](#) and [Regulations](#)**, email: [FEED\\_MILL\\_INSP@inspection.gc.ca](mailto:FEED_MILL_INSP@inspection.gc.ca)
- **For questions about DELs**, email: [DEL\\_Questions\\_LEPPP@hc-sc.gc.ca](mailto:DEL_Questions_LEPPP@hc-sc.gc.ca)
  - For more information about obtaining an Establishment Licence, click [here](#).
- **For questions about dispensing, licensing or other rules within your province/territory**, contact your provincial/territorial authority directly.