



Health Santé  
Canada Canada

Canadian Food Inspection Agency  
Agence canadienne d'inspection des aliments

## FACT SHEET: SELLING PRESCRIPTION MEDICATED FEED

### Responsible use of Medically Important Antimicrobials for Veterinary Use

#### CONTEXT

As of December 1, 2018, all [Medically Important Antimicrobials \(MIAs\) for veterinary use](#) will be sold by prescription only. The objectives of the change in prescription status are to ensure:

- veterinary oversight to support antimicrobial stewardship and food safety and
- appropriate traceability and record keeping related to the prescription and sale of these drugs.

This fact sheet provides to Commercial Feed Mills (CFMs) and medicated feed distributors guidance regarding the regulatory requirements for the sale and distribution of prescription medicated feed. It should be read in conjunction with the fact sheet: *Accessing and Selling Prescription Veterinary Drugs*, in which Health Canada confirms that CFMs may be considered “wholesale druggists” under the *Food and Drug Regulations*.

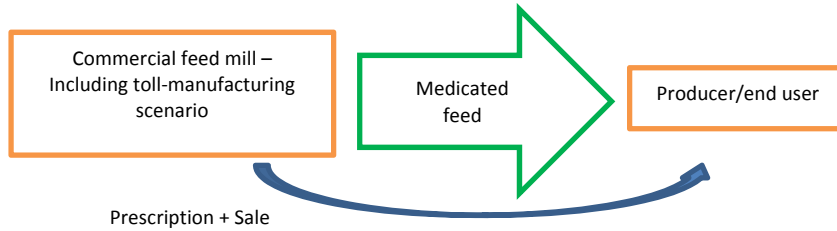
As a result of the change to prescription status of MIAs, the number of medicated feed prescriptions issued by veterinarians and received by CFMs will increase significantly. There will be implications for the sale and distribution of approximately 340 veterinary antimicrobials approved by Health Canada. Approximately 75 MIAs approved in Canada are for use in animal feed. This represents about 70-80% of the total volume of all MIA drugs sold in Canada. Business models (i.e., CFMs, shippers, third party distributors) exist to facilitate the movement of bulk quantities of medicated animal feed from the CFM to the farm.

#### TERMINOLOGY

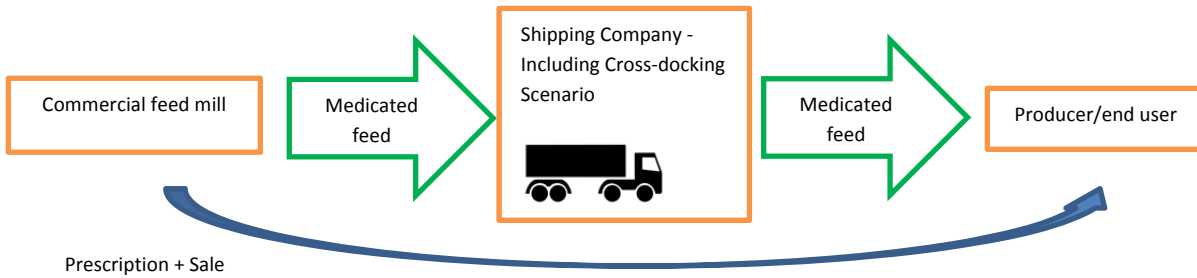
- This fact sheet is intended for those **commercial feed mills (CFMs) that are conducting activities as wholesale druggists**: “Commercial feed mill” does not currently have a regulatory definition. For the purpose of this fact sheet, a commercial feed mill is considered a wholesale druggist under the *Food and Drug Regulations*, and is a facility that mixes and manufactures medicated feed for commercial sale in accordance with the *Feeds Act and Regulations*.
- For the purpose of this fact sheet, **cross-docking** is an activity that facilitates the sale of feed (including prescription medicated feed) by providing storage and delivery services between the commercial feed mill and end user/producer. This helps particularly in remote locations for end user pick-up, or for further delivery to the end user/producer.
- For the purpose of this fact sheet, **toll-manufacturing** is the manufacturing of a feed (including prescription medicated feed) that is contracted out from the commercial feed mill (who received the order) to another/separate facility. This helps particularly when there is a capacity challenge and the need for special equipment.
- **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 in feed. For clarity of this fact sheet, the term used is “**DIN drug premix**”.

## CURRENT PATHWAYS AND CONDITIONS FOR SELLING PRESCRIPTION MEDICATED FEED\*\*

### Pathway 1: Direct sales between a CFM and producer



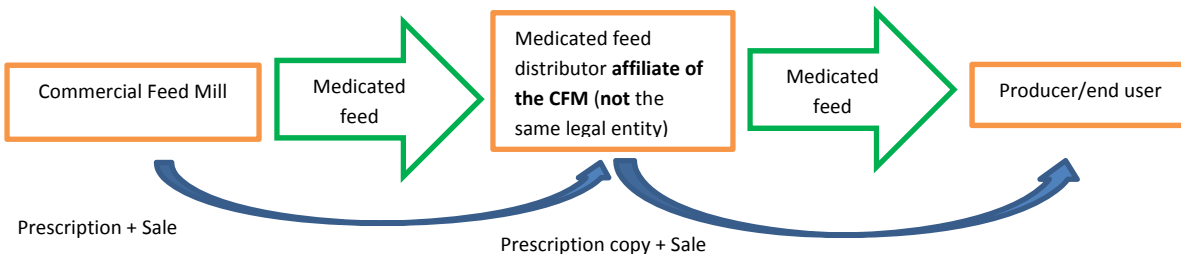
### Pathway 2: Sales that are facilitated by a shipping company



### Pathway 3: Sales that are facilitated from a CFM by another facility that is the same legal entity as the CFM



### Pathway 4: Sales that are facilitated from a CFM by a third party distributor



**\*\*It is important to note that these pathways have not changed, they are simply now applicable to a wider range of in feed medications that have been given prescription status.**

## Regulatory requirements and other non-regulatory conditions

The *Food and Drug Regulations* and the *Feed Regulations* contain provisions that govern the sale of drug premixes and medicated feed. The following points are intended to provide greater clarity about how regulatory requirements can be met by CFMs, shippers and medicated feed distributors involved in the sale of prescription medicated feed:

- CFMs can access prescription drugs to be mixed into feed (DIN drug premix) from the manufacturer or another wholesaler without a prescription.
- Further sale activities by CFM or the distribution pathways illustrated are limited to prescription medicated feed (i.e. not DIN drug premixes or other prescription drugs).
- A veterinary prescription is required at the time of sale from the CFM for prescription medicated feeds made in accordance with the Compendium of Medicating Ingredients Brochure (CMIB). For those not made in accordance with the CMIB, a veterinary prescription is required prior to manufacturing.
- The prescription medicated feed can only be sold to the producer for whom the prescription was issued.
- The CFM may hire a company to transport the prescription medicated feed to the producer. The medicated feed being transported must be specific to the producer, as indicated on the prescription provided at the time of sale/invoice.
- The CFM can facilitate the sale at any of their own facility locations (same legal entity; pathway 3) by processing the order for the prescription medicated feed (i.e. providing the prescription and invoice, and coordinating the required delivery date) based on the prescription provided by the producer. Mixing of the feed as well as the record keeping for sale and prescriptions must be done at the CFM.
- For the affiliated medicated feed distributor pathway (Pathway 4), a legal agreement must exist between the CFM and the affiliated medicated feed distributor related to facilitating sale on behalf of the CFM.
- Appropriate traceability and record keeping related to the sale of the prescription medicated feed must be maintained throughout the chain (by the CFM and if applicable, by the affiliated medicated feed distributor). All invoices related to any prescription medicated feed are to include:
  - Name of the producer to whom the prescription medicated feed has been sold
  - Address of the farm where the animals to be treated are located (i.e. where the feed will be used)
  - Name and quantity of the prescription medicated feed
  - Name and address of the CFM where the feed was manufactured
- A copy of the prescription must be kept on file by the CFM and if applicable, by the affiliated medicated feed distributor for a duration of either:
  - 2 years after the last date the feed was sold for on-label medicated feed (i.e. following the CMIB)
  - 1 year after the last date the feed was sold for off-label medicated feed (i.e. not following the CMIB)
- The prescription medicated feed must follow all applicable *Food and Drug Regulations* and *Feed Regulations*
  - If the prescription medicated feed is **on-label** (i.e. following the CMIB), the label does not need to contain the veterinary prescription information, but must meet all other requirements set out in the [Feeds Regulations](#).
  - If the prescription medicated feed is **off-label** (i.e. the veterinarian prescription does not correspond to the CMIB), the label must meet all requirements set out in the [Feeds Regulations](#) for a veterinary prescription feed.

## INDEPENDENT RETAILERS

Consistent with the fact sheet: Accessing and Selling Prescription Veterinary Drugs, if a company solely operates as an independent retail feed store, they cannot access or sell prescription drugs in any form (including as prescription medicated feed) to anyone, even with a prescription. They can continue to access and sell non-prescription drugs in any form (including as medicated feeds).

## FLOORSTOCKING PRESCRIPTION MEDICATED FEED AT A COMMERCIAL FEED MILL

A CFM can manufacture and floorstock prescription medicated feed if the feed is manufactured and labelled in accordance with the CMIB (i.e. on-label medicated feed).

A CFM can floorstock medicated feed and sell it to a producer or an affiliated medicated feed distributor once the order and prescription has been received. It can also be sold to another CFM without a prescription, provided that CFM also conducts similar activities of manufacturing medicated feed and meets the definition of a wholesale druggist.

An affiliated medicated feed distributor cannot floorstock prescription medicated feed for sale to the general public. Any prescription medicated feed that is in their facility must have an associated prescription.

## LINKS TO OTHER RESOURCES

Animal Nutrition Association of Canada website- [Sales and Dispensing of prescription DIN drug premixes and prescription medicated feed](#)

[Health Canada Website: Promoting the Responsible use of Antimicrobials](#) in Animals and CFIA Web site: [How is the CFIA contributing to the responsible use of medically important antimicrobials in animals.](#)