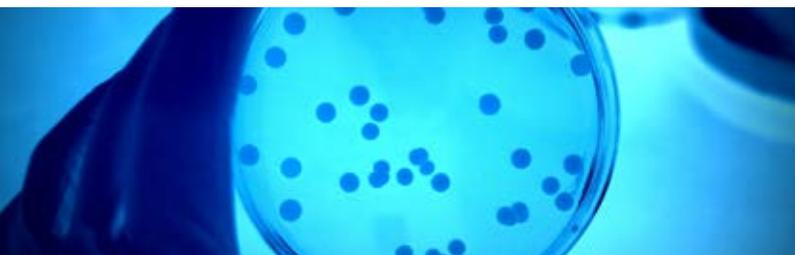


December 1, 2018 Antimicrobial Policy Change **Frequently Asked Questions**



As of December 1, 2018, all category I, II and III antimicrobials will be on Health Canada's Prescription Drug List. This Fact Sheet addresses common questions from the feed industry related to this policy change.

If we sold category 4 DIN drug premixes directly to producers before December 1, 2018, can we continue to sell these products after December 1, 2018?

YES. Nothing is changing for category 4 antimicrobials. All of the products in category 4 which are currently approved by Health Canada as over-the-counter drugs, will remain over-the-counter drugs after December 1, 2018. For a list of all category 4 drugs, [click here](#).

What is the difference between a veterinary prescription feed and a medicated feed containing a prescription product?

The *Feeds Regulations* has different requirements for medicated feed which contain off-label drugs and those which contain drugs as per the CMIB. All in-feed medications (including prescription or over-the-counter) approved by Health Canada are included in CMIB.

A veterinary prescription feed is a feed that is manufactured pursuant to a veterinary prescription and is not in accordance with the CMIB i.e. it is off-label, which means it is for a dose, species or combination of drugs not approved on product labels in Canada and therefore not in the CMIB. These feeds must meet all requirements for labelling of a veterinary prescription feed as per the *Feeds Regulations*.

A medicated feed containing a prescription product is a feed which contains a medication which has a Pr status and is included in the CMIB. These feeds can be manufactured by CFM's without a prescription and can be floorstocked by a CFM. However, CFM's can sell these products only when the prescription has been obtained. These feeds are labelled in the same manner as any other feed medicated with a medication as per the CMIB.

If a prescription received from a producer is for a dose and species that is in the CMIB, however the veterinarian's feeding instructions, cautions and/or warnings does not match the CMIB. How should this feed be treated?

This feed would be considered an off-label/off-CMIB feed and hence considered a veterinary prescription feed and the information on the veterinary prescription will be given preference over the information in the CMIB.

Can an on-farm feed mill sell products it manufactures as well as distribute feeds to its own farms?

A facility that manufactures and sells its medicated feed products is considered to be a commercial feed mill and is subject to all the associated regulatory requirements and CFIA inspection activities. A facility that is a commercial feed mill can only purchase prescription medications for use in feeds that will be sold. If the facility wishes to distribute feeds to its own farms it will need to separate the feed mill enterprise from the on-farm activities and will then need to ensure there is a record of the sale along with a prescription for all prescription medicated feeds it sells or distributes.

Are "integrators" (persons who manufacture feed to be fed to livestock owned by them but fed and managed by another party contracted to do so), considered as Commercial Feed Mills and is the movement of feed to the contracted party considered to be a sale?

The activities of an integrator are considered to be commercial in scope by the CFIA and thus the facility is deemed to be a commercial feed mill and subject to the associated regulatory requirements and CFIA inspection activities. Records of manufacture and sale as well as prescriptions would be required as well as the other regulatory requirements such as labelling and distribution records.

The following Q&A addresses the sale of medicated feed containing prescription products via dealer networks.

What is an affiliated medicated feed distributor?

In the feed industry, an AMFD is often referred to as a dealer/ dealership. These independent businesses have an ongoing and direct business relationship with a commercial feed mill and sell feed which is manufactured by that commercial feed mill. These dealers are subject to inspection by the Canadian Food Inspection Agency and must meet all the requirements of the *Feeds Regulations*.

What is meant by “a legal agreement must exist between the CFM and the affiliated medicated feed distributor” to sell Pr medicated feed?

A legal agreement between the CFM and AMFD in this context should include the following elements:

1. The AMFD is facilitating the sale to its clients on behalf of the CFM.
2. The CFM’s should only sell medicated feed containing prescription products to the AMFD once the AMFD has received an order from their customer and has the veterinary prescription in hand for that order.
3. The AMFD agrees to only sell medicated feed containing prescription products to the producer for whom the feed was sold to the AMFD by the CFM for.
4. The AMFD will not sell medicated feed containing prescription products to another producer nor will they floorstock any medicated feed containing prescription products in their facility.

When a CFM sells a medicated feed containing a prescription drug product to an AMFD, what requirements must they meet?

1. For feeds medicated according to the CMIB, the CFM must have the order for the feed (producer name, type of feed and quantity) as well as the veterinary prescription in hand before **selling** the feed to the AMFD.
2. For feeds not made in accordance with the CMIB (i.e. extra-label drug use), the CFM must have the order for the feed (producer name, type of feed and quantity) as well as the veterinary prescription in hand before **manufacturing** the feed.
3. The CFM’s invoice to the AMFD must include:
 - a. Name of the producer to whom the prescription medicated feed has been sold
 - b. Address of the farm where the animals to be treated are located (i.e. where the feed will be used)
 - c. Name and quantity of the prescription medicated feed
 - d. Name and address of the CFM where the feed was manufactured

I am an AMFD who wants to sell medicated feed containing prescription products to my customer, what do I need to know?

1. You must have a legal agreement with the CFM from who you are able to purchase the medicated feed from.
2. You can only order the veterinary prescription feed and a medicated feed containing a prescription product from the CFM, once you have received the order from your customer and the prescription for that order.
3. You **cannot** floorstock any medicated feed containing prescription products in anticipation of an order from a customer.
4. You must keep adequate records to demonstrate that the feed which you bought from the CFM has been sold to the customer for whom you ordered the feed and provided the CFM with a prescription for.
5. You cannot sell a medicated feed containing prescription products ordered for a specific customer to another customer.
6. You must keep the prescription on file for the length of time determined by the regulations (2 years after the last date the feed was sold for on label medicated feed (i.e. following the CMIB) and 1 year after the last date the feed was sold for off label medicated feed (i.e. not following the CMIB)

I am a CFM and have been asked to sell a medicated feed containing prescription products to an AMFD. However, I do not feel comfortable signing a legal agreement with this customer. What do I do?

A CFM is not obligated to engage in a legal agreement with an AMFD. Therefore, if you are not comfortable doing this, you can continue to sell non-medicated feed or feed medicated with OTC products to the AMFD but you cannot sell the veterinary prescription feed or a medicated feed containing a prescription product.

Does the CFM or AMFD need to keep the veterinary prescription on file?

Yes, BOTH need to keep. The CFM must keep the veterinary prescription on file to demonstrate they have sold the product according to the veterinary prescription. The AMFD must keep the prescription on file to ensure traceability from the CFM to the AMFD and down to the customer.

Can a third party independent consultant access and sell prescription medicated feed from a toll manufacturer for an end user/producer?

As described in the fact sheet, the third party independent consultant does not meet the conditions indicated for being the same legal entity of or affiliated medicated feed distributor with a commercial feed mill and thus would not be able to access a prescription medicated feed from a toll manufacturer or a CFM for an end user/producer.