

## Changes to Health Canada's Prescription Drug List: Getting Ready for Changes in Veterinary Oversight Requirements

On December 1, 2018 prescription requirements for medically important antimicrobials come into effect. This regulatory change is part of Health Canada's move to strengthen the oversight of veterinary drugs, including antimicrobials. This is part of Health Canada's policy initiative to promote responsible use and increase veterinary oversight of medically important antimicrobials.

### For Alberta broiler producers, the biggest impacts will be:

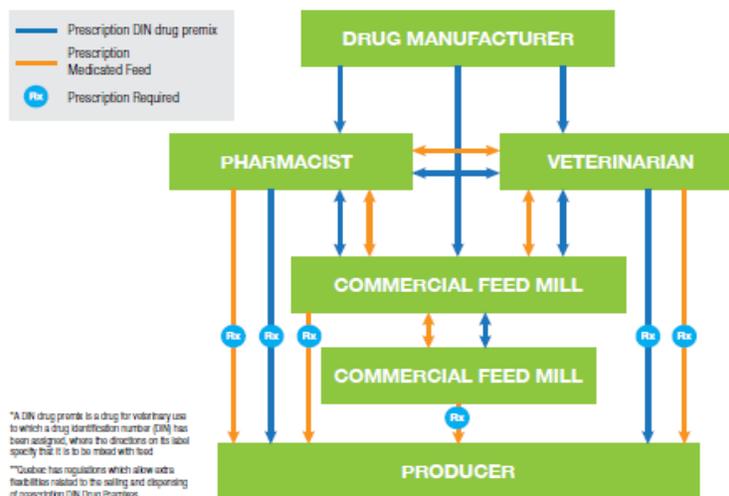
- veterinary prescriptions will now be needed for feed-based antimicrobials,
- antibiotics you used to be able to purchase over the counter will now only be available by prescription for an authorized dispensary, and
- on-farm feed mills may have to change how they purchase medication

### Here's what you need to know...

#### Can I still use medicated feed?

- Yes. If the veterinarian determines that there is a need for use of antibiotics for disease prevention, medicated feed can still be used. There MUST be veterinary involvement in this decision, as the feed mill cannot sell you the feed without presentation of a prescription.
- The intent behind both the Health Canada policy change and CFC's voluntary move to discontinue use of antibiotics for disease prevention is to reduce overall use of antibiotics, so producers, nutritionists, and poultry health practitioners should focus on improving animal health through best management practices and alternatives to antibiotics to reduce the need for antimicrobials. Currently the majority of antimicrobials are given to broilers in the feed.

#### How will prescription requirements affect my access to medication or to medicated feed?



- Health Canada’s regulatory changes to strengthen veterinary oversight of antibiotics used for animal health is part of a global initiative to reduce misuse of antibiotics
- As of December 1, 2018, all medically important antimicrobials will require a prescription from a veterinarian. This includes prescription requirements to purchase medicated feed.
- As of December 1, 2018, medications can only be purchased from an authorized veterinary dispensary or pharmacy. Over the counter purchases of prescription products at “Authorized Medicines Sales Outlets” will no longer be permitted.
- Together, these changes will align animal health practice with the human health practice, where antibiotics are only available through a prescription.

### What medications are affected by these changes?

- All in-feed medically important antimicrobials require a Prescription prior to sale for on-label products. Some of these medication previously only needed a prescription if they were being given extra-label or in combination with other medications.
- ~340+ products implicated in all dosage forms across all agricultural animal species, with about 75 of these being in-feed products
- Some typical poultry feed antibiotics now used for the prevention of disease are listed below. These antibiotics are also affected by CFC’s voluntary bans of Category 2 (end of 2018) and Category 3 antimicrobials (end of 2020) for use of these antibiotics for prevention of disease. A complete list is also included below. Please note that your veterinarian can still prescribe any of these medications for treatment of disease.

### Antimicrobial Classification System

*Public Health Agency of Canada*

Category	Importance to Humans	Criteria
I	Very High Importance	Essential for serious human infections; few or no alternatives; may be last resort
II	High Importance	Variety of infections, including serious ones. Few alternatives.
III	Medium Importance	Alternatives generally available
IV	Low Importance	Not used for humans

### Classification of Poultry Antibiotics

Category	Examples of Agriculture AMU*
I	<ul style="list-style-type: none"> <li>• Ceftiofur (Excenel™) – extra-label</li> <li>• Baytril™ – extra-label</li> </ul>
II	<ul style="list-style-type: none"> <li>• Viginiamycin (e.g. Stafac™)</li> <li>• Lincomix™, Lincomycin™</li> <li>• Tylan™</li> <li>• Uniprim™ – extra-label</li> <li>• Romet™ – extra-label</li> <li>• Penicillins (e.g. Pot-Pen™, Super Booster™, Pen-P™)</li> </ul>
III	<ul style="list-style-type: none"> <li>• BMD™</li> <li>• Sulphonamides (e.g. Sulfa™)</li> <li>• Tetracyclines</li> <li>• Neomycin</li> <li>• Apralan™ – extra-label</li> </ul>
IV	<ul style="list-style-type: none"> <li>• Ionophores (e.g. Rumensin™, Monteban™, Maxiban™, Sacox™, etc.)</li> </ul>

\*Based on the 2002 Uses of Antimicrobials in Food Animals in Canada, Impact on Resistance and Human Health report of the Advisory Committee on Animal Uses of Antimicrobials and Impact on Resistance and Human Health, Veterinary Drugs Directorate.

### Can I still purchase over the counter medications after December 1?

No. Medications can only be purchased if you have a veterinary prescription. Many places you used to be able to purchase over the counter medications from do not currently meet the Alberta Veterinary Medical Association’s (ABVMA) for prescribing or dispensing medications. Some are working with the ABVMA to make this possible, but may not be ready by December 1.

### How can my veterinary prescriptions be filled?

Once you have a veterinary prescription, you can have this filled at veterinary clinic or pharmacy that handles the animal medications being prescribed. If your veterinarian does not sell the product, they can help you figure out where to get it.

### **Can I still use my existing supply of medications after December 1?**

Yes, but after December 1, you will be expected to be able to demonstrate the use of the medication was prescribed by a veterinarian. CFC's ban of the use of Category 2 antimicrobials for the prevention of disease begin on January 1, 2019. From that point, your OFFSP / Animal Care program auditor will expect to only see prescriptions for Category 2 antimicrobials for the treatment of disease rather than the prevention of disease. Use of Category 3 antimicrobials are allowed for either the treatment or prevention of disease, but only with a veterinary prescription.

### **What is veterinary oversight?**

Veterinary involvement in flock health decisions regarding medication and health practices applies their professional expertise to your farm within the broader context of local and industry health challenges. This oversight includes:

- Element of antimicrobial stewardship
- Professional involvement of licensed veterinarians in providing direction for appropriate use of antimicrobials in animals
- Objective of ensuring prudent use
- Veterinarians, through their education, experience and accountability, provide guidance or direction for appropriate use and distribution of antimicrobials.

### **What are the requirements for veterinary prescription?**

- A registered veterinarian makes an informed decision that a particular drug will be prescribed
- Establishes the medical needs of the patient - individual animal or group of animals
- Pertinent medical history and conducting a physical examination
- Not necessary that an individual animal is examined in every instance
- Veterinarian MUST have relevant medical knowledge to support the establishment of medical need.

### **Can I call any veterinarian for a prescription?**

- In Alberta, many veterinarians do not have poultry expertise and will therefore not have the relevant medical knowledge to work with your farm. While some producers may have access to a veterinarian that works with their processor, many others do not.
- Broiler producers will have to ensure they have a working relationship with a veterinarian who is familiar with their operation and its' health challenges. A veterinary-client-relationship (VCR) is needed for a veterinarian to prescribe medication.

### **What is a veterinary-client-relationship?**

A Veterinary-client-relationship (VCR) exists when all of the following conditions have been met:

- The veterinarian has assumed responsibility for making clinical assessments and recommendations regarding the health of the animals and need for medical treatment,
- The veterinarian has sufficient knowledge of the animals on which to base the assessment, diagnosis and treatment of the medical condition of the animals. This means that the veterinarian:
  - is professionally acquainted with the keeping and care of the animals, and
  - has documented relevant and timely interaction between the veterinarian, animal owner or caretaker and animal patients, and
  - has documented medically appropriate information and knowledge about the animals
- The client has agreed to follow the veterinarian's recommendations and prescription.
- The veterinarian is available or has arranged for follow-up evaluation, especially in the event of adverse reactions or failure of the treatment regimen.

### **Can I still access veterinary services without a veterinary-client-relationship?**

Yes. You can still have a veterinarian come out to your farm or submit birds to their office for diagnosis. This service has not changed. It is much like the walk-in medical clinic you might go to if you do not have a regular medical doctor. However, this process may not be as timely as it could be if you had an ongoing VCR and an Animal Health Protocol (flock health plan). Through these changes we are moving away from a simple VCR on an individual flock basis to a VCR on a farm basis.

### **Do I need to involve the vet for every flock?**

- No. With an Animal Health Protocol in place, you can have prescriptions in place for expected disease issues specific to your farm, region, or time of year. This eliminates the need for the veterinarian to work with multiple flocks facing the same disease challenge in repeated flock cycles.
- An Animal Health Protocol is similar to the Flock Health Plan described in the recent updates to our broiler Animal Care Program.

### **What is a Farm Animal Health Protocol?**

Producers can work together with their veterinarians to develop ongoing animal health protocols (flock health plan). As part of the protocol, they can anticipate seasonal or site-specific animal health issues that could require medication rather than waiting until after the disease appears.

- An animal health protocol is a series of steps to be undertaken following an indication.
- Veterinarians may establish animal health protocol(s) in advance or anticipation of the animal health event
- Establishes the medical need for issuing a prescription.
- An animal health protocol is not a prescription
- When an animal health protocol includes a step that a drug be administered to an animal or group of animals, a legitimate prescription must be issued before pharmaceuticals are dispensed.
- This allows a prescription could be filled and on-hand in anticipation of a condition(s).

If you have an existing relationship with a veterinarian and have concerns about disease challenges specific to your farm, please approach them to discuss the development of a Farm Animal Health Protocol. Some veterinarians are already working on them for their clients.

### **Can a veterinarian prescribe medication if they have never been to my farm?**

The limited number of poultry veterinarians in Alberta and distances that must be travelled can make it challenging to get a veterinarian on-site. As long as the requirements for prescription are met, a veterinarian with familiarity with your operation (through your VCR) may not have to be on site. The requirement for physical examination and diagnostics could be done on submitted samples in these cases.

Veterinarians working for processors will have a good awareness of the health challenges of their group of producers. This can simplify the process of fully developing your VCR and Animal Health Protocols.

### **Can a feed mill stock medicated feed?**

- There will be no restriction on manufacturing (floor stocking) of medicated feeds if manufactured pursuant to Health Canada approvals. This allows the feed to be available for immediate use. Note that this applies only to feed medications being used according to label requirements.
- Restrictions remain if manufacturing a medicated feed in a manner deviating from Health Canada's approvals and veterinary prescriptions will continue to be required prior to manufacturing (i.e. no floor stocking).

### **How do I purchase medicated feed?**

- Feed mills are allowed to floor-stock medicated feeds, but can only sell them to you if you can provide a prescription.
- Commercial Feed mills can continue to dispense "mixed feed" containing MIAs pursuant to a prescription; typically, medications containing MIAs (with a Drug Identification Number (DIN)) can be mixed into feed and dispensed by Commercial Feed mills as:
  - Medicated Complete feed
  - Medicated Supplement
  - Medicated Macro Pre-mix
  - Medicated Micro Pre-mix
- The Alberta Veterinary Medical Association (ABVMA) will address concerns about prescriptions and dispensing of medications. While the CFIA has oversight over the activities of feed mills, the ABVMA has oversight over any veterinary practice operating on-site.
- Note that a veterinary prescription will be required prior to sale when a drug is mixed in livestock feed.
- Note also that Category IV antimicrobials such as ionophores and other medications to prevent coccidiosis are not subject to veterinary oversight and therefore do not require a prescription

### **How can on-farm feed mills access medications needed for feed?**

- On-farm mills may need to adjust production practices to meet these requirements.
- With a veterinary prescription, you will be able to buy medicated complete feeds, supplements, macro pre-mixes, or micro pre-mixes from commercial feed mills. However, you can only purchase the source drugs for on-farm mixing from a veterinarian or pharmacist.
- Ability to purchase drug product (DIN) with a prescription is possible, but it is not clear yet how readily available these medications will be and if this will be a cost-effective route.

### **How can I get prescription medications to the farm?**

- Veterinary practice entities may ship appropriately prescribed and dispensed pharmaceuticals.
- Appropriately prescribed and dispensed pharmaceuticals may only be shipped by a veterinary practice.
- Drop shipping, or shipping of pharmaceuticals from the distributor or manufacturer directly to a client's place of residence or business, does not constitute appropriate dispensing.
- A farm representative may pick up and deliver prescriptions to your site. This includes people such as family members, processor/hatchery field staff, and others.

### **How much difference does the use of antibiotics for disease prevention make in production costs?**

- Antibiotic growth promotion (AGP) research in the 1950s demonstrated overall response to AGPs was inversely-proportional to well-being of experimental animals. Medication had less effect in good flocks.
- There is also a dampening effect when housing, hygiene, nutrition, and health optimized.
- Based on North American biosecurity and farm technology, the impact of the loss of antibiotics for growth promotion or disease prevention would be approximately 1%. This is much lower than that of parts of the world with lower quality management and barns, and is also much lower than the expected impact on the swine and beef industries.
- The impact of loss of access to antimicrobials could be greater for poultry producers with more frequent health challenges due to the state of their buildings, local or seasonal challenges, and management issues leading to poor brooding, inadequate culling, lack of control over environmental conditions, etc. This can be addressed through a combination of working with your veterinarian on a flock health plan (which could include medication under certain conditions) and minor adjustments to management.

### **What are the trends in antibiotic use in farm animals?**

- Practice of feed administration of these Antibiotic Growth Promoters (AGPs) at non-therapeutic concentrations has increased by 10- to 20-fold since the 1950s.
- Without caps or reductions, global use of antibiotics in animal agriculture is expected to increase by an additional 30% by 2030.
- The World Health Organization (WHO) recommends ban of non-therapeutic use of AGPs, veterinary oversight (prescription-based system) and monitoring of antimicrobial resistance in bacteria.
- These changes are not unique to Canada. This year Vietnam and Thailand joined the list of countries banning use of antibiotics for growth promotion and there is a significant increase in research on products or practices that could be used to replace antibiotics used to promote growth or for disease prevention.

### **Why is Health Canada making these regulatory and policy changes?**

- Antimicrobial resistance, or AMR, is an important issue that has complex and widespread consequences for both human and animal health.
- Development of AMR can lead to the loss of access to effective antimicrobials.
- Agriculture must continue to promote the responsible use of antibiotics – both to address global health concerns and to ensure agriculture continues to have access to antimicrobials that continue to be effective in the treatment of disease.

### **How will these changes help chicken producers?**

- Federal changes to promote responsible use and veterinary oversight of medically important antimicrobials will help preserve the effectiveness of these drugs for as long as possible.
- Recent Health Canada surveillance of poultry farms, processing plants, and retail products has demonstrated a decrease in antimicrobial resistance (AMR) to the Category 1 antimicrobials broiler producers stopped using in 2014.
- Surveillance for drug use and evidence of AMR could contribute to additional changes to veterinary oversight and access to antimicrobials.
- Responsible use of antibiotics leads to improved consumer confidence and to the meeting of market access requirements