Canada's Industry & Regulatory Framework: An ongoing policy initiative to enhance responsible use of Veterinary Antimicrobials

Dr. Egan Brockhoff

Veterinarian, Prairie Swine Health Services. #10 4845 79th Street, Red Deer, Alberta, Canada, T4P 2T4
Veterinary Counselor, Canadian Pork Council

1. Introduction

Infections resistant to antimicrobials have become increasingly difficult to manage. Concern over the emergence and rapid spread of antimicrobial-resistant (AMR) infections has been lain firmly at the foot of human and veterinary medicine. The Government of Canada has committed to taking action to prevent, limit and control the emergence and spread of AMR infections. In response, Canada's livestock and veterinary communities have affirmed their commitment to being part of the solution to this global concern.

Health Canada's efforts to strengthen Canada's regulatory framework for veterinary antimicrobials began anew in 2014 with the issuance of a Veterinary Drug Directorate (VDD) guidance on antimicrobial claims. Label claims relating to production enhancements and growth promotion would be phased out and over-the-counter medicated feed additives of medical importance would be moved to prescription only. This guidance was soon followed by the release of the Federal Action Plan on Antimicrobial Resistance and Use in Canada. The focus of Health

Canada's efforts has been to increase regulatory oversight of the approximately 1.6 million kilograms of antimicrobials distributed annually for veterinary medicine in Canada. Initially, their goal was to have implementation by December of 2016, a date in line with similar regulatory changes in the United States. Unfortunately, a complex set of federal and provincial Acts and Regulations and Policies all needed to be updated prior to Canadian implementation. The first of the regulatory amendments came into effect in November of 2017.

Beginning in 2014, Health Canada started actively and routinely engaging with a diverse set of stakeholders as they moved towards strengthening policy initiatives to enhance the responsible use of antimicrobials. This multi-sectoral approach has resulted in the release of the Pan-Canadian Framework on AMR, the publication of Canada Gazette II – amendments to the Food and Drug Regulations, the release of the Federal Framework on Antimicrobial Resistance and Use in Canada, and the Action plan on Antimicrobial Resistance and Use in Canada. Wanting to ensure that farm families had a seat at the table, the Canadian Pork Industry has been working closely with the respective stakeholders to ensure the voice of our industry is actively heard in these discussions, consultations and publications.

There have been six core regulatory and policy initiatives undertaken in this multi-sectoral approach that will lead to changes in antimicrobial oversight. The pork industry, along with the veterinary community and other stakeholders, have been actively involved in helping shape these initiatives and policies.

They are:

- Increasing oversight on importation of veterinary drugs (Own Use Importation or OUI)
- Increasing oversight on importation and quality of active pharmaceutical ingredients (APIs)
- Mandatory reporting of sales volume from manufacturers and importers to support antimicrobial use surveillance
- Facilitating access to low risk veterinary health products (VHPs), as additional tools for the maintenance of animal health and welfare
- Removing growth promotion claims from medically-important antimicrobials (MIAs)
- Increasing veterinary oversight over all MIAs (Prescription status switch)

2. Oversight of OUI

Currently veterinary drugs, including over the counter antimicrobials, can be imported into Canada for personal use purposes with limited restrictions. The new regulatory amendments that came into force November 13th 2017 prohibits importation of drugs not approved in Canada, with an exception for specified drug products that represent an acceptable risk to food safety and public health. These exempted products will be established and maintained by Health Canada on a product list referred to as List B. Products on List B must fit the following criteria:

- Is not a prescription drug for veterinary use in Canada
- Is in its final dosage form and within its commercial packaging

- Is not a medicated premix
- Is not a medically important antimicrobial
- Is approved by a recognized foreign regulator
- Has an established MRL in Canada for the active ingredient and species
- Has similar directions for use as a product approved in Canada with a DIN
- Has no unresolved safety issues

Livestock associations will be responsible for submissions to the Veterinary Drug Directorate (VDD). Individual producers will not be eligible to submit directly to the VDD.

3. Veterinary Health Products (VHPs)

No regulatory provisions currently exist for the sale of low risk veterinary health products. Creating a risk-based regulatory pathway to allow importation and sale of low risk veterinary health products for use in animals, including food animals, was initiated in 2015. This regulatory amendment will allow for drugs in dosage form that are not manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal sate or its symptoms to be marketed in Canada. VHPs will only be permitted to state that they may “maintain or promote the health and welfare of” the defined species and animal type.

4. Veterinary APIs

The use of APIs in Canada is unique in the developed world. Currently, there is extremely limited oversight on the importation of antimicrobials as APIs for use in food animals and veterinary medicine. Manufacturers, importers and compounders of APIs for veterinary use are not required to have a Drug Establishment License (DEL) or to follow Good Manufacturing Practices (GMPs).

Beginning May 17th 2018 all APIs for use in veterinary medicine must be manufactured according to GMPs used in human drug manufacture. Manufacturers will require a DEL. Pharmacists and Veterinarians who wish to manufacture must also have a DEL and adhere to GMPs.

5. Mandatory Reporting of Antimicrobial Sales Volume

Beginning March 31st 2019 all sales data from the previous year must be reported, including 2018 sales volumes. Importers, manufacturers and compounders will all be required to follow this new regulation.

6. Removal of Growth Promotion Claims

To enhance the prudent use of medically important antimicrobials in animals, Health Canada is working with stakeholders to phase out non-prudent uses for long-term non-therapeutic purposes, namely growth promotion and weight gain. Since 2004 there have been no new growth promotion claims approved for MIAs. In Canada, 64 products will be affected by this regulation change. Since 2014,

manufacturers have been working with Health Canada to establish new prevention and treatment label claims so no products will be lost to Canadian veterinarians and producers. The Canadian livestock industry has been fully supportive of this initiative.

7. Increasing Veterinary Oversight of all MIAs

To promote prudent use, Health Canada is moving all remaining MIAs to prescription status via the Prescription Drug List (PDL). Health Canada believes that the involvement of a licensed veterinarian in treatment decisions is an important part of antimicrobial stewardship. These new regulation changes will impact approximately 340 products in dosage form in Canada with 75 of those being in-feed MIAs. Al MIAs will be prescription as of December 1st 2018.

For in-feed medications all approved MIAs, including OTC and Pr, will be moved and included in the CFIA's Compendium of Medicated Ingredients Brochure (CMIB). A veterinary prescription will be required prior to sale when an MIA drug is mixed in livestock feed. There will be no restriction on manufacturing (floor stocking at feed mills) of such MIA medicated feeds if manufactured pursuant to Health Canada approvals, i.e. as per the CMIB. If medicated feed is being manufactured in a manner deviating from Health Canada's approvals, a veterinary prescription will be required prior to manufacturing, i.e. no floor stocking at feed mills. Feed mills will no longer be permitted to sell MIAs in dosage form.

8. Canadian Pork Council Drug & Vaccine Use Policy

The Drug Use Policy of the Canadian Quality Assurance program reflects the pork industry's commitment to the responsible and proper use of veterinary pharmaceuticals in food animals. It recognizes the importance of food safety, antimicrobial resistance and the necessity of being transparent in order to maintain public trust in Canada's pork producers.

Canadian Pork Producers are proud to raise the healthy hogs needed to produce wholesome, high-quality pork. Producers understand their role in mitigating the development of antimicrobial resistance and are committed to the responsible and prudent use of antimicrobials. Antimicrobials are a key tool in maintaining animal health and welfare. Canadian Pork Producers are proud to promote a one-health sustainability model; healthy people, living and working with healthy animals for a healthy planet.

The objectives of the CQA™ Drug Use Policy are:

- Food Safety: To ensure the proper usage of veterinary products to prevent drug residues in pork.
- Antimicrobial Resistance (AMR): To encourage the responsible usage of antimicrobials in order to reduce the development of antimicrobial resistance that could pose a risk to human and/or animal health.

- Antimicrobial Stewardship: To demonstrate that Canadian Pork Producers are committed to antimicrobial stewardship and the sustainable use of antimicrobials.

The Canadian Pork Council, in cooperation with provincial and industry stakeholders, has developed a new drug use policy to better reflect the current and proposed regulatory framework. This policy includes commitments to eliminating the use of antimicrobials from growth promotion, restrictions of the use of Class I antimicrobials in API format and the use of Class I antimicrobials for treatment purposes only and not prophylaxis.

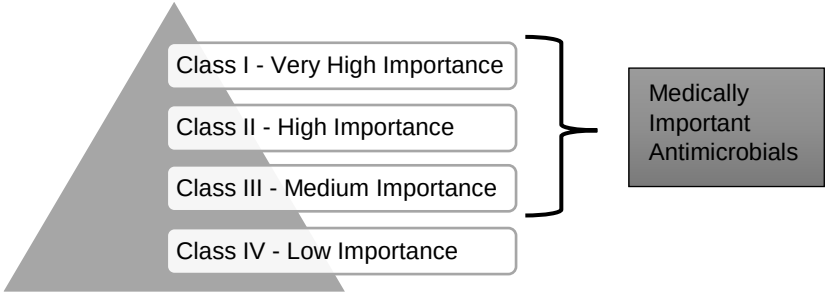

Figure 1. Classes of medically important antimicrobials (MIA)

9. Closing

The Government of Canada is currently taking a significant number of steps to address AMR and AMU. Implementation of these steps began this past November and will continue over the next two years. The Canadian Pork Industry wants to ensure that farm families have access to these important tools both now and in the future. Antimicrobials are one of many tools important to the production of safe and wholesome pork and in helping to maintain high standards of animal welfare in the

face of infectious disease. Through awareness, education and cooperation Canadian Pork Producers and the Veterinary community have committed to doing their part to ensure prudent and responsible usage.