CANADIAN MEAT COUNCIL
CONSEIL DES VIANDES DU CANADA

By e-mail only:
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September 14, 2016

Mr. Bruno Rodrigue
Office of Legislative and Regulatory Modernization
Policy, Planning and International Affairs Directorate
Health Canada
Address Locator: 3105A
Holland Cross, Tower B, 5th Floor
1600 Scott Street
Ottawa, ON KIA 0K9

Dear Mr. Rodrigue:

Re: Regulations Amending the Food and Drug Regulations (Veterinary Drugs – Antimicrobial Resistance), *Canada Gazette* Part I, July 2, 2016.

On behalf of its member companies, the Canadian Meat Council ("CMC") welcomes the opportunity to respond to Health Canada's proposal to amend the *Food and Drug Regulations* (Veterinary Drugs – Antimicrobial Resistance). Some our members will also provide comments on this regulatory proposal to Health Canada.

The Canadian Meat Council has been representing Canada's federally inspected meat processing industry since 1919. Recording annual sales of $23.6 billion, exports of $5.7 billion, and 65,000 jobs, the meat industry is the largest component of Canada's food processing sector. As owners of livestock and poultry

as well as suppliers of meat products to consumers, CMC members are committed to reducing the risk of antimicrobial resistance.

Generally speaking, the Canadian Meat Council supports the significant step that Health Canada has taken to strengthen and modernize regulatory oversight of veterinary drugs. Health Canada's regulatory proposal has the merit of encouraging a more prudent use of antimicrobials in food producing animals by drawing on the World Health Organization's (WHO) two key essential elements to combat the development of antimicrobial resistance (AMR), namely the assurance of the drug's quality through Good Manufacturing Practices (GMPs) and measures to control the misuse of veterinary drugs by restricting the importation of unauthorized veterinary drugs for own use in food-animal producing animals. However, the CMC wishes to highlight that enhanced regulatory oversight of veterinary drugs should not translate into cumbersome regulatory requirements, compelling organizations to focus too narrowly on regulatory compliance to the detriment of brokering knowledge and facilitating innovation to counter the loss of antimicrobial effectiveness.

While we understand that the proposed regulatory amendments are complementary to additional important policy initiatives currently underway, including the removal of growth promotion claims of antimicrobial drugs and the change of status of some antimicrobial drug from over the counter to prescription, we note that significant issues need to be addressed to further strengthen Canada's regulatory framework for veterinary antimicrobials. In this context, the CMC endorses the efforts of its members in identifying specific issues for consideration by Health Canada. They are listed on the attached feedback form.

When considering whether this proposal can be effectively implemented, care must be taken to ensure that federal regulatory and policy initiatives are interconnected and mutually supportive through intra- and inter-departmental collaboration to restrict the use of antimicrobials in the form of Active Pharmaceutical Ingredients (APIs) and facilitate access to approved antibiotic alternatives. In the case of the latter, we are not only referring to veterinary health products (VPHs) which are essentially just natural health products but also "low risk vet health products" and topical treatments which are under a distinct Health Canada veterinary drug policy and feed additives with physiological effects regulated by the Canadian Food Inspection Agency under the *Feeds Act* and *Regulations* which are currently undergoing a modernization process.

The implementation of this regulatory initiative also calls for enhanced federal, provincial and territorial collaboration and coordination efforts. Ensuring the quality of the drugs through GMPs should be a consistent requirement for manufacturers, veterinarians and pharmacists importing APIs for use in veterinary medicine. Currently, there is no uniform regulatory approach in Canada for distribution and dispensing of APIs. This has significant implications on the federal government's ability to restrict the importation of unauthorized veterinary drugs for own use in food-animal producing animals.

The Regulatory Impact Analysis Statement (RIAS) fails to recognize that veterinarians and pharmacists have been importing "large quantities" of API for use in food animal production. The RAIS does not acknowledge the role of pharmacists in dispensing, under prescription, APIs to animal owners.

It is critical that quality in the compounding of APIs be assured in the amended regulations to prevent the development of antimicrobial resistance, prevent occurrences of violative residues, and maintain consumer trust. To address this gap, an additional objective of this regulation should require pharmacists to compound in accordance with an Established Licence (EL) or, at a minimum, through the supply of a DIN product to mitigate the risk to human health by reducing the likelihood of resistance to antimicrobials in humans as a result of the use of antimicrobials for veterinary purposes. Moreover, only identical product to the Canadian approved product should be imported.

The CMC believes that all veterinary drugs administered to food animals should be commercially manufactured under intensive quality controls, provided in proper dosage forms, contain up-to-date labelled safety and withdrawal information, and be used under veterinary oversight to effectively reduce the risk of AMR as a public health threat in Canada. Because of the variability in approach to regulating veterinary drugs in Canada, the CMC also believes that implementation details be discussed with all impacted government and industry stakeholders on an-going basis to meet regulatory objectives and to help promote a smooth transition.

This concludes the comments of the Canadian Meat Council on Health Canada's AMR regulatory proposal. We are at your disposal to meet with you to discuss our comments in more detail.

Sincerely,

Suzanne Sabourin
Director, Legal and Regulatory Affairs

Att.

c.c. Simon Kennedy, Deputy Minister
Paul Glover, Associate Deputy Minister
Anil Arora, Assistant Deputy Minister, Health Products and Food Branch