



August 29, 2016

Marc Legrand
Senior Policy Analyst
Veterinary Drugs Directorate
Health Canada
11 Holland Avenue - Ground Floor, Suite 14
Ottawa, Ontario K1A 0K9

Dear Marc,

Re: Antimicrobial Resistance Policy Initiatives and Regulatory Proposal

On behalf of the Beef Farmers of Ontario (BFO) and our 19,000 producer members, thank you for the opportunity to provide comments on the Veterinary Drugs Directorate's antimicrobial resistance (AMR) initiatives, including proposed amendments to the *Food and Drug Regulations*. BFO represents Ontario's beef farmers by advocating in the areas of policy planning, industry development and research, and domestic and export market development.

BFO supports Ontario beef farmers in their decisions to use approved products in their production programs, as well as the decisions made by Health Canada in determining what products can be used safely. Ontario's beef farmers are concerned about the issue of antimicrobial resistance, and BFO recognizes that the imprudent use of antimicrobials in human and animal medicine could contribute to resistance and affect our future ability to treat people or animals who require antibiotic treatment. However, beef farmers feel that it can sometimes be a challenge to achieve a balance between decreased antibiotic use and animal welfare.

We share the objective of moving towards use of antibiotics in cattle that is prudent and sustainable, while minimizing the potential for negative impacts on animal and human health. Antimicrobials are an important tool in protecting animal health and well-being, with the vast majority of antimicrobials used in beef production classified in Category IV: Low Importance. Prophylactic drug use is a very effective animal health option for certain operations with a vet-client-patient relationship (VCPR) in place, and should be maintained as an option to prevent more severe disease. This option reduces the need to use more powerful antimicrobial drugs of higher medical importance to treat and cure disease that has progressed and become more serious.

The establishment of clearer guidelines and requirements around own use importation (OUI), growth promotion claims, veterinary oversight and good manufacturing practices for medically important

... /2



antimicrobials is, in general, a positive development. However, it is important that proposed changes have no increased regulation cost for producers, and no negative impacts on industry's competitiveness in the global marketplace. For this reason, BFO would urge that the new administrative requirements being placed on producers, producer associations, drug manufacturers, distributors, compounders and veterinarians are carefully considered and weighed, so as to not place undue administrative and regulatory burden on industry. For example, a straightforward process with specified timelines should be available to producers who wish to apply for a product to be added to the exemption list of veterinary drugs that are permitted for OUI.

BFO strongly encourages continued efforts to harmonize the drug approval processes and statuses in Canada and the United States. There needs to be a streamlined and affordable process for veterinary drugs to get approved in Canada, and this includes capitalizing on appropriate opportunities to recognize other countries' approvals of veterinary drugs as a way to achieve approval in Canada. We do not want a situation where producers are compromising the welfare of their animals or their competitiveness with other jurisdictions because they don't have access to sufficient treatment options.

As growth promotion claims are phased out in Canada, it is critical that prudent steps are taken to ensure that there is no loss of treatment options as a result of this policy change, and that drug companies are not given any reason to pull their products from the Canadian market as they wait for clarification on labelling approvals and requirements.

In addition, research initiatives regarding antimicrobial resistance and the development of new veterinary drug products must be prioritized and allocated the necessary resources and funding. It is essential that an appropriate level of products and treatment options for all diseases and disorders be available in the Canadian marketplace and obtainable by a producer with a VCPR, as needed. Sufficient, verifiable and replicated research is also needed in order to justify and support any proposed changes regarding antibiotic use before decisions are made or promoted.

BFO would like to thank Health Canada for the opportunity to comment on the proposed AMR initiatives and amendments to the *Food and Drug Regulations*. We encourage Health Canada and the Veterinary Drugs Directorate to continue engaging stakeholders, including beef farmers and agriculture at-large, in this important discussion on antimicrobial use and resistance.

Sincerely,



Matt Bowman
President

cc: BFO Board of Directors

