CVMA Comments on Health Canada’s Proposed Veterinary Drug Regulatory Change

Active Pharmaceutical Ingredients (API)

Own Use Importation (OUI)

General:

- The Canadian Veterinary Medical Association (CVMA) supports a proposed new approach by Health Canada’s Veterinary Drug Directorate that would allow appropriate oversight on the importation of active pharmaceutical ingredients (APIs) and on the importation of veterinary drugs by individuals for use on their own animals (OUI) into Canada. Antimicrobial resistance is a major threat to the continued availability of effective antimicrobial treatment of bacterial disease in animals and humans, and these changes will help Canada to meet international standards in antimicrobial use in animals.
- The CVMA has been urging Health Canada to make regulatory changes to close loopholes that were identified in 2002 as very high priorities by the Health Canada Advisory Committee on Animal Uses of Antimicrobials and Impact on Resistance and Human Health. The CVMA is part of the Ad Hoc Committee for Antimicrobial Stewardship that grew out of the 2011 national conference on Antimicrobial Stewardship in Canadian Agriculture and Veterinary Medicine. The Conference identified Canada’s existing regulations around API and OUI as the second highest priority issue requiring urgent attention and change. As they currently exist, the API and OUI provisions essentially make antimicrobial drug use in animals in Canada unregulated and pose serious risks to animal health, public health and food safety (CVMA Position on Importation of Veterinary Drugs attached).
- The CVMA has consulted with the Canadian Association of Bovine, Poultry and Swine veterinarians to ensure the feedback from the veterinary community on this important issue is comprehensive and complete. The following is a summary of the CVMA comments on the specific issues:

1. **Active Pharmaceutical Ingredients (APIs):** The CVMA understands from the draft Health Canada proposal that API importation would be regulated so as all API would enter Canada by permit to holders of establishment licenses only. This permit system would effectively require importers of APIs to meet manufacturing standards of veterinary drug license holders. This would also eliminate the importation of API
by livestock producers and companion animal owners, which would serve to mitigate the many risks of the direct administration of raw chemicals of unknown quality to animals. The CVMA supports the regulatory intent of the permit system that allows access to API for legitimate manufacturing purposes only, however some questions and concerns remain:

I. How will this proposed regulatory change impinge on the practice of veterinary medicine, as currently veterinarians can legally compound using APIs? Compounding using APIs is meant to be last resort when following the CVMA Compounding Guidelines and Decision Cascade (i.e. only if there is no approved veterinary or human drug), and there are legitimate situations when veterinarians need to compound drugs to address an urgent animal health issue.

II. Would veterinary practitioners have a regulatory exemption in place so they can access APIs when there is no other treatment alternative than to compound a drug?

III. If veterinarians do not have access to APIs for compounding under the proposed permit system, will they still have access drugs compounded from APIs through compounding pharmacies if necessary (i.e. will this permit system restrict pharmacy access)?

2. **Own Use Importation (OUI):** The CVMA understands from the draft Health Canada Proposal that rather than closing the OUI regulatory loophole completely, that there would be a mandatory permit system implemented for importation of select food animal OTC products (e.g. cattle endectocides and implants) but VDD Category I,II, and III antimicrobials would not be eligible for importation. The CVMA views the change to make antimicrobials ineligible under the OUI policy a significant step forward, as they represent a higher risk to animal health, public health and food safety, however the CVMA does have the following questions and concerns:

I. There is currently a lack of effective regulatory enforcement by the Canadian Border Services Agency (CBSA) for veterinary drug importation. A system that allows only select drugs to be imported by permit does not fulfill the regulatory modernization goal of CBSA ‘resource efficiency’ that will enhance/facilitate effective enforcement. The CVMA and CABV have addressed the issue of effective enforcement previously ([CVMA/CABV/CAHI letter to CBSA is attached](#)) and the response from CBSA was that OUI “inherently presents unique challenges to the CBSA’s interdiction efforts”.
Given the current level of CBSA veterinary drug regulatory enforcement, it is unlikely that CBSA would be able to determine which products should be able to enter the country and which ones cannot.

II. The Health Canada proposal states that there must be veterinary practitioner involvement in the permit application that the livestock producer submits. Producers must name the ‘veterinarian in charge’ and veterinary oversight is a ‘requirement’ of permit issuance. This puts veterinarians in an awkward position of having to ‘sign off’ on an unapproved product when an approved product exists with Canadian labeling (e.g. withdrawal times, bilingual, dosing). If withdrawal intervals differ, between the Canadian approved product and the unapproved imported product, which time applies? Who takes responsibility for a residue violation that involves an unapproved product that the veterinarian has provided oversight for? Will the list of permitted drugs have withdrawal times that are endorsed by the VDD so that veterinarians have information they can provide producers?

III. OUI is not only a risk to animal health, public health and food safety, but also is a risk to trade in food animal products. European trading partners are beginning to examine Canadian regulations around importation and use. A recent example is the European Union (EU) audit of the Ontario Dairy industry where EU inspectors examined the conditions under which Canadian dairy products are produced from farm to table. As a result of the audit, the Canadian federal government was informed that the lack of oversight of veterinary drug use in dairy cattle in Ontario was unacceptable. The proposed OUI permit system may not serve to satisfy Canadian trading partners that Canada has the required level of oversight to be compliant with their trade requirements.

IV. The proposed OUI permit system for Canada is not harmonized or aligned with drug regulatory authorities internationally (other ‘recognized or trusted’ countries). The OIE Tool for Evaluation of Veterinary Performances measures the level of advancement of regulation of veterinary medicines (http://web.oie.int/downld/SC/EN_OIE%20PVS%20Tool_2008.pdf). Using this evaluation tool, the proposed OUI permit system would likely score no more than Level 2 - ‘limited capability to exercise administrative control over the usage, including import and production, of veterinary medicines and veterinary biologicals’ (page 26).
The CVMA appreciates Health Canada’s efforts to resolve the important issues that surround OUI and API importation – issues the CVMA has had concerns with for many years. However, as pointed out, some of the proposed regulatory changes raise further questions and present new and equally encumbering challenges that must be discussed and overcome before the veterinary profession can fully support this framework. The CVMA looks forward to working with Health Canada to further advance this proposed regulatory model and resolve these outstanding issues.