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Warren Skippon, Manager
National Issues and Animal Welfare
c/o Canadian Veterinary Medical Association
339, Rue Booth Street
Ottawa, ON K1R 7K1

Dear Warren:

Re: Veterinary Drug Regulation Modernization - Active Pharmaceutical Ingredients and Drug Importation Through the Own Use Importation Policy

The CABV/ACVB appreciates the opportunity to comment on this important matter. We had a good response from our Executive for feedback, which I will attempt to summarize in this letter.

Active Pharmaceutical Ingredient (API) Importation:

Some members of the CABV/ACVB Executive had questions about the requirements necessary to become an establishment license (EL). Who would be able to become an EL? This is certainly not completely clear when reading through the documentation.

There were no major concerns expressed about the potential for the regulatory change to impact veterinarians using API's in compounded products as this was not seen as a significant issue for bovine practitioners. Several members of our executive expressed the opinion that API use in bovine practice was exceedingly rare and that as long as licensed compounding pharmacies had access to API's if required, it would not have any significant impact on bovine veterinarians.

Own Use Importation (OUI):

Our Executive was unanimous in the opinion that the creation of a two-tiered list of items "allowed for importation" (OTC) and "not allowed for importation" (antimicrobials) would make the desired outcome of "keeping it simple" for the Canadian Border Services Agency (CBSA) extremely difficult. When this issue was last communicated by CABV and CVMA, the response from CBSA was that OUI "inherently presents unique challenges to the CBSA's interdiction efforts". Given the current level of enforcement, it is unlikely that CBSA would be able to determine which products should be able to enter the country and which ones cannot.

In addition, it was thought to place the veterinarian in a very difficult and awkward situation to have to sign off on permits for OUI. This appears to us that Health Canada is attempting to offload responsibility

to veterinarians, potentially putting veterinarians in a difficult position when they are unwilling to endorse permits for legitimate reasons not perceived by clients as valid. Much of the OUI that occurs is driven by pharmaceutical pricing, which the CVMA position statement clearly states is not a satisfactory reason for allowing importation of pharmaceuticals.

Our members were quite concerned about the food safety implications of having to sign off on these "OTC" products that might be imported. If withdrawal times differ between the Canadian product and the foreign product with equivalent active ingredient, which withdrawal time applies, and who takes liability for this? If the veterinarian signs off on an imported product, and there is a residue violation with that product, is the veterinarian liable?

If the VDD would like veterinarians to oversee this, it would be necessary to make a complete list of permitted products, with withdrawal times approved by the VDD. This would take the responsibility off of individual veterinarians to make the call on specific products for import.

Our Association certainly supports the position statement of CVMA that "OUI carries inherent food safety and animal health risks as well as risks to trade in food animal products." We agree with the CVMA position statement that cost advantages are not a valid reason for importing products through the OUI provision.

Thank you once again for the opportunity that you have provided to the CABV/ACVB to comment on these important matters to our profession.

Kind regards,

Melodie Chan

Dr. Melodie Chan
President, CABV/ACVB

JC:pmm