CANADIAN VETERINARY MEDICAL ASSOCIATION
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Cost Recovery Renewal Initiative
Resource Management and Operations Directorate
Health Products and Food Branch
Health Canada
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To whom it my concern, via mail and e-mail: CRI_IRC_Consultations@hc-sc.gc.ca

The Canadian Veterinary Medical Association (CVMA) appreciates the opportunity to provide input to Health Canada on the Fee Proposal for Drugs and Medical Devices. In addition to the feedback provided in this letter, the CVMA along with the Canadian Animal Health Institute (CAHI) raised a number of issues during a Sector Specific Session hosted by Health Canada on November 23, 2017.

The CVMA has several concerns and suggestions regarding Health Canada's Fee Proposal for Drugs and Medical Devices:

1. Canada is a small market for animal health product representing about 2.5% of the global market. The cost to register a new food animal drug in Canada is currently very expensive, approaching $250,000 with additional costs to companies if multiple species use is sought. There are public good benefits as well as benefits to companion animal owners and the general public in Canada from having access to health management tools that ensure animal welfare and in the case of production animals, food safety. Any increase in fees must consider the public good. As such the industry should not bear the burden of paying the majority of registration costs.

2. The CVMA fears that increasing registration fees could well result in a decline in submissions filed by companies and possibly the cancelling of registrations already in progress. The net result could be a greater risk of unlicensed animal drug use through Emergency Drug Release (EDR) and illicit importation and/or compounding of drugs.

3. Changes to registration fees would have implications for the Health Canada workforce if the EDR requests increase steeply; if there is a need to manage a steep increase in drug shortages; or if enforcement must be increased due to increased compounding and concerns regarding extra-label drug use (ELDU).

4. Should manufacturers in fact be required to pay a higher proportion of fees, they should expect that the regulator's services and service standards be modernized such that the processes become much more efficient and the registration turnaround times be significantly reduced. For example, the CVMA supports that if the veterinary review fee schedule is to be modernized, it also incentivise availability of licensed products in a small Canadian market. This is particularly important for supplementary submissions, potential RCC reviews, Minor Use Minor Species (MUMS) such as in aquaculture and small ruminants, alternatives to antimicrobials and niche products. In addition the CVMA supports considering the recognition of reviews from competent foreign agencies and reduced regulatory burden for companion animal products.

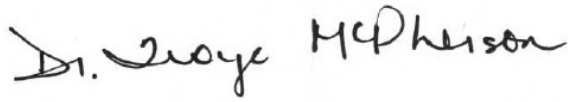
5. In line with the above, the CVMA suggests that Health Canada aim to directly assist pharmaceutical companies seeking either MUMS approvals of a drug already approved for small ruminants in another country, or to support joint collaborative approvals of new drugs with other countries such that occurred recently with meloxicam - simultaneously approved in Canada, New Zealand and Australia for sheep. It is important that the goal to reduce the need for extra-label drug use in food animals be protected and furthered through a well-funded MUMS program.

In short the CVMA has concerns that the above implications for manufacturers could result in unintended consequences that would negatively impact animal health and food safety. The CVMA strongly supports veterinarians being able to access effective animal health products for the benefit of their clients and patients. The limited resources in the existing regulatory system should not be put under the extra pressure that would result from the proposed fee increases, as outlined above.

The CVMA urges Health Canada to proceed with caution as it reviews its fee schedule and that its analysis include consideration of the benefits of facilitating the availability of safe and effective animal health products in the Canadian marketplace for the public good.

Once again, thank you for the opportunity to comment.

Sincerely,



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