



July 30, 2019

Mr. Etienne Ouimette
Director General
Resource Management and Operations Directorate
Health Products and Food Branch, Health Canada
Cost Recovery Office

via email: hc.cro-brc.sc@canada.ca

Re: Proposed Veterinary Pre-market Evaluation fee structure

Dear Sir,

The Canadian Veterinary Medical Association (CVMA) greatly appreciates the opportunity to comment on the proposed Veterinary Pre-market Evaluation fee structure as published in Canada Gazette, Part 2 on May 8, 2019. The CVMA appreciates the need for Health Canada to examine the potential to recover some or all of its costs, however our association is greatly concerned that implementation of the proposed fee structure would have negative implications for animal health and welfare in Canada over the coming years.

The CVMA provides a national and international forum for over 7,400 veterinarians working in all of Canada's provinces and territories as private practitioners, researchers, educators and public servants. In addition, the CVMA counts 7,800 veterinary technicians and technologists as affiliate members. Members of the veterinary community have a broad knowledge base including expertise in animal health and disease; knowledge and understanding of the biology of domesticated animals; practical experience and understanding of the care and management of animals; practical experience in the recognition of signs of suffering in animals; and an understanding of the interdependencies that exist between animal health, human health and the environment.

Veterinary practitioners provide services to owners of pets, livestock and other animals. In addition to their contributions to public health and food safety, veterinarians help farmers market healthy and humanely- raised animals which are vital to Canada's reputation as a producer and exporter of billions of dollars of high-quality animals and animal products.

In order to provide excellent veterinary care and support for animal health and welfare, veterinarians require safe and effective tools including veterinary pharmaceuticals approved for use in Canada. Such tools must be readily available to veterinarians for them to address the global health challenges faced by their clients and patients.

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The proposed Veterinary Pre-market Evaluation Fee Structure would clearly result in an increase in drug review and maintenance fees over the next few years. Based on its analysis (July 2019) of the proposal, the Canadian Animal Health Institute (CAHI) concluded: “The new veterinary drug fees are not competitive and will have a significant negative impact on the availability of veterinary drugs when fully implemented. Specifically, when taken together the service fees for veterinary drug reviews, drug establishment licenses (DEL), and maintenance in the market by one Canadian veterinary drug company found that if implemented as is:

- sales for 58% of the current livestock products will not support a new registration due to review, DEL and maintenance fees; and
 - 52% of companion animal product sales will not support being introduced and/or maintained in the Canadian market for the same reasons.
 - If innovation costs of 5% of the total research and development (R&D) costs are included in the calculation
 - 79% of the livestock products; and
 - 74% for companion animal
- fall below the financial threshold to support product registration and launch in Canada.”

CAHI concludes that in addition to the fees being higher than countries such as Australia, “The fees are not in-line with Canada’s Economic Roundtable for Agri-Food to have “an agile regulatory system that supports innovation, provides certainty to industry, and protects health and safety.”

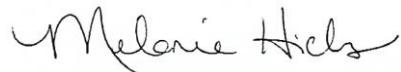
The CVMA is very concerned Canadian veterinarians could lose access to animal health products that are currently available and would never gain access to products licensed in countries such as the USA since registration and maintenance costs in Canada’s relatively small market would be prohibitive. Such a situation would have negative implications for both Canada’s livestock and pets.

In addition, the current proposal could undermine the Government of Canada’s efforts to coordinate stakeholder initiatives under the federal Pan-Canadian Framework on Antimicrobial (AM) Resistance and associated federal Action Plan. The CVMA has a particular interest in this initiative given the recent approval by the Minister of Agriculture and Agri-Food Canada of its proposal for a four-year project for a National Veterinary Oversight System for Antimicrobial Use (NVOS) which will focus on AM Stewardship and AM Use Surveillance. The CVMA is concerned that without enough available, safe and effective antimicrobials and alternatives, other less desirable options may be sought by some including increased use of compounded drugs, extra-label drugs use, or even illegal importation.

We respectfully ask that Health Canada carefully consider our comments and weigh the potential implications of the current proposed fee change.

The CVMA would be pleased to meet with Health Canada officials any time to discuss the above concerns.

Sincerely,



Dr. Melanie Hicks
CVMA President

SR:MH/ds

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