



Canadian Animal Health Institute's Eight Recommendations to Health Canada on Regulatory Fees for Veterinary Drugs

Extracted from the CAHI's Feedback Submitted to Health Canada on July 25, 2019

The new fees imposed by Health Canada are thought by policy makers to better reflect the value of services provided to the manufacturers and distributors of veterinary drugs; however, CAHI believes the new fees do not reflect the true business realities facing our sector. The regulatory program needs to be competitive based on market size to other international programs and may include the need to stop performing some of the regulatory activities currently undertaken to streamline internal Health Canada processes.

CAHI appreciates that Health Canada provided the veterinary drug sector a seven (7) year lead-in to the new fees and included a Small Business Strategy, but these modifications are not enough. Our analysis shows that the increased fees from 39-500% by 2027 will result in the loss of, or significant price increases for, 80 to 90% of registered veterinary medicines.

As recommended by the Economic Roundtable, Health Canada need to review the impact all regulations, technical guidance and associated policies to ensure they are ***necessary, appropriate and effective*** in achieving intended objectives in the most cost-effective manner possible. Alternative service delivery opportunities, compliance strategies that recognize a key trading partner's assessment of product safety, and third-party accreditation need to be considered for all products.

- 1. Discontinue Companion Animal Product Reviews and Product Life Cycle Management for Veterinary Drugs Licensed by Trusted Regulators and Substitute with an Administrative Fee for Acceptance of the Submission** – The review of veterinary drugs for companion animals does not support the healthcare system and pets in the developed countries generally are cared for similarly. Furthermore, Canada does not regulate pet foods, some of which make quasi drug claims, so why should it regulate veterinary companion animal drugs the extent it does? It is the recommendation of the CAHI that Canada accept foreign reviews and maintenance decisions from trusted regulatory authorities (e.g. USA, EU, UK) for companion animal drugs. Quality standards would need to be aligned with the trusted regulatory authority requirements and companies selling companion animal products would need to attest to meeting those standards.

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- 2. Modernize Manufacturing and Quality Reviews Through Use of Foreign Decisions by Trusted Regulatory Authorities** – As mentioned earlier, Canada is only 2.5% of the global market. Consequently, products most often get manufactured for the global market and not just solely for the Canadian market. To ensure product availability in the Canadian market there is a need for alignment with our trusted regulatory authorities and the standards they administer. Again, acceptance of foreign reviews from trust regulatory authorities would help to build in efficiencies and cost savings into the regulatory fee process and support product availability.
- 3. Modernize Clinical Efficacy Reviews Through Use of Foreign Decisions by Trusted Regulatory Authorities** – Expanding on the above recommendations, foreign decisions should be used to build in review efficiencies for species such as poultry and swine, which have relatively standardized production practices in developed countries.
- 4. Modernize the Fee Structure to have Incentives for Minor Use and Minor Species (MUMS) Submissions** – Any fee structure must include MUMS submissions. MUMS products are offered at a cost to the animal health companies as a service to veterinarians and animal owners. The current fee structure does not support companies in developing a business case to accommodate MUMS; in fact, the schedule does not even recognize MUMS as veterinary drug use. Presently these fees are considered on a case-by-case basis and are not transparent or consistent. We would recommend an 80% reduction in review and maintenance fees for MUMS products due to the limited sales of these products and with an assumed lower risk due to the small volumes used.
- 5. Modernize the Fee Structure for Joint and Shared Reviews** – For the joint and shared reviews with other Trusted Regulatory Authorities, CAHI recommends a reduction in the review fees by 50%. Joint and shared reviews are important foundations to veterinary drug alignment of labels between countries, availability of product for animal owners and supportive of trade in food animal products because farmers have access to the same health management tools.
- 6. Incentives for Small to Medium Sized Companies (SME) Need to be Expanded** – Any veterinary drug sponsor that is a SME, regardless of whether it is a global affiliate or not since all companies and/or divisions must have business accountability, needs to be encouraged to bring new product to the Canadian market. Canadian based companies should be encouraged to do R&D using Canada as the first registration that could be recognized elsewhere.
- 7. Incentives for Alternatives to Category I, II, and III Medically Important Antimicrobials** – To support the reduced need for antimicrobials in veterinary medicine there should be a 50% reduction in the review fees for alternatives to antimicrobials.
- 8. Component-Based Fee Structure Needs to be Maintained** – CAHI supports the component-based fee structure presently in place since it more accurately reflects the true cost to government for the services it delivers and is closely aligned with the EU and Australian fee structures for veterinary drug regulatory services.

In closing CAHI trusts that there will be opportunity to have meetings with Health Canada officials to discuss the above eight recommendations as these fees are to be reviewed annually. The Canadian Animal Health Product Regulatory Advisory Committee (CAHPRAC) would be a useful body to facilitate a regulatory modernization discussion. We believe the modernization changes outlined above for Canada's veterinary drug program will help to create and maintain good jobs for the middle class and build economic prosperity that will ensure a safe and bright future for all Canadians and the animals we care for.