Canadian Animal Health Institute

Institut canadien de la santé animale

SUBMISSION FOR PRE-BUDGET CONSULTATIONS IN ADVANCE OF THE UPCOMING FEDERAL BUDGET

Prepared by Canadian Animal Health Institute

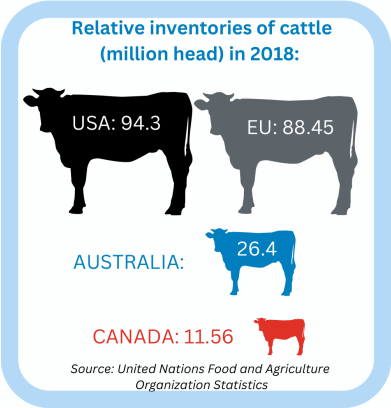
- **Recommendation 1**: That the government amend the fees related to the veterinary drugs services policy outlined in Fees in Respect of Drugs and Medical Devices Order SOR/2019-124 in the Food and Drugs Act to the amount that would make Canada proportionally competitive to key trading partners.

- **Recommendation 2**: That the government amend the Food and Drug Act to allow foreign decisions by trusted regulatory authorities in other jurisdictions for Manufacturing, Quality and Clinical Efficacy Reviews related to the authorization of veterinary drugs.

- **Recommendation 3**: That the government amend their policies in order to abolish Drug Establishment License (DEL) fees for low-risk Active Pharmaceutical Ingredients (API).

Availability of Veterinary Medicines in Canada

Over the last five years, Canada has seen a 40% decrease in licensed veterinary medicines (DINs) availability due to Canada's regulatory environment. The Fees in Respect of Drugs and Medical Devices Order SOR/2019-124 in the Food and Drugs Act aligns Canada's veterinary drug regulations with significant animal health markets. This makes veterinary product development, introduction, and maintenance increasingly challenging.



Currently, Canadian veterinarians and producers have access to fewer licensed veterinary drugs than they did in 1983, and both livestock producers and veterinarians are growing alarmed at the impact this is having on animal health, food safety and sustainability in the agricultural sector.

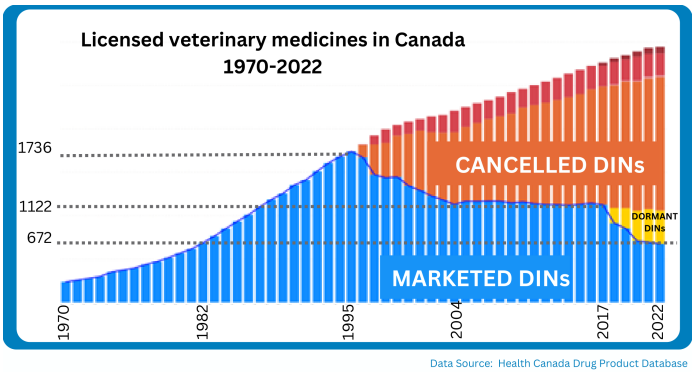
The global animal health market is projected to grow at a compound annual growth rate (CAGR) of 3.6% from 2022-2027, reaching $57.54 billion by 2027. Canada, representing only 2.5% of global sales in the animal health market, is vulnerable to external influences, particularly the growth of the veterinary vaccine market, without benefiting from it. In 2018, Canada had 11.56 million cattle compared to 94.3 million in the US, 88.45 million in the EU, and 26.4 million in Australia, hindering its ability to compete effectively in the global livestock agriculture industry due to limited access to veterinary medicines. The country's regulatory fees act as a barrier to entry for veterinary drug producers, encouraging them to enter larger markets. Urgent regulatory reform is necessary to enhance animal health, food security, sustainability, and the competitiveness of the Canadian agricultural sector.

About Canadian Animal Health Institute (CAHI)

The Canadian Animal Health Institute (CAHI) is the preeminent trade association representing Canada's developers, manufacturers, and distributors of animal pharmaceuticals, biologics, feed additives, veterinary health products, and animal pesticides. As a national association, CAHI's membership comprises over 60 companies categorized as Full Members and Associate Members, responsible for nearly 95% of the country's animal health product market. CAHI's mission is to promote the timely availability of safe and efficacious animal health products that contribute to the well-being of animals and ensure a safe and productive food supply.

Recommendation 1: Health Canada Service Fees

The decline in available veterinary drugs in the Canadian market has negative implications for animal welfare, veterinary medicine quality, and the sustainability and competitiveness of the livestock industries. Veterinarians and producers resort to alternative strategies to access unavailable products, such as compounded products, off-



Data Source: Health Canada Drug Product Database

label drug use, own-use importation, and online purchases from other countries. These practices pose severe risks to animal health, environmental safety, and food safety, which could impact trade and international borders for Canadian livestock exports. Ensuring the availability of veterinary medicines is crucial for sustainable food production, as animal health products play a vital role in the well-being of animals, human health, and the planet. The ability of the animal health industry to innovate within the Canadian regulatory environment is essential to achieve the desired outcomes of antimicrobial resistance plans and UN Sustainable Development Goals by 2030. As of 2022, 384 Drug Identification Numbers (DINs) are dormant and at risk of permanently leaving the Canadian market, emphasizing the challenges in the highly regulated yet small market.

On April 1, 2020, SOR/2019-124 came into effect, introducing up to 500% fee increases for regulatory reviews of veterinary drugs in Canada. These higher fees surpass those of similar markets like Australia and the EU, making it challenging for Canadian veterinary drug companies to compete globally. The smaller Canadian market size also hinders the return on investment for veterinary drug development, further impacting the availability and affordability of essential veterinary medicines. The government has an opportunity to adopt alternative approaches to regulatory oversight, considering foreign decisions and virtual inspections, to sustain the livestock industry and ensure access to vital veterinary drugs.

This presents a unique opportunity for the government to adopt lessons learned from COVID-19 to reduce the costs of regulatory activities in the future without sacrificing the safety or efficacy of drug products licensed in Canada. This is a vital opportunity to sustain our livestock industry financially and self-regulatory. Examples of alternative approaches to regulatory oversight include:

- Use foreign decisions by trusted regulatory authorities in other jurisdictions for Manufacturing, Quality and Clinical Efficacy reviews for all products.
- Use of virtual inspections for DEL sites producing low-risk APIs
- Modernization of fee structures for joint and shared reviews
- Discontinuation of product reviews, product life cycle management and the associated fees for companion animal drugs licensed by trusted regulators, to be replaced with an administrative fee for submission of the foreign decision(s)

Such approaches would support effective regulatory oversight of veterinary drugs in Canada, recognizing the realities of Canada's small market size and the public good that veterinary drugs provide in terms of supporting food safety, human health and the human-animal bond while still facilitating the registration of new products and product maintenance in the marketplace.

Recommendation 2: Foreign decisions and Trusted Regulatory Authorities

Health Canada's Veterinary Drugs Directorate actively participates in international regulatory cooperation and knowledge-sharing with other jurisdictions worldwide. However, the current stagnation of 384 Drug Identification Numbers (DINs) due to federal government actions leaves the Canadian animal health industry vulnerable to potential exclusion from the global market. This stagnation has particularly affected the dairy industry, where regulatory requirements prevent the use of the injectable short-acting antibiotic oxytetracycline (SA-OTC) to treat pneumonia and mastitis in cattle. Consequently, eight products have already been or are at risk of being cancelled. The Canadian Animal Health Institute (CAHI) urges a review of these regulatory amendments to safeguard Canada's competitive position in dairy farming and ensure access to vital veterinary medicines. By considering the standards established by trusted regulatory authorities in other jurisdictions for Manufacturing, Quality, and Clinical Efficacy Reviews related to veterinary drug authorization, Health Canada can support livestock well-being and maintain the country's competitiveness in the global animal health market.

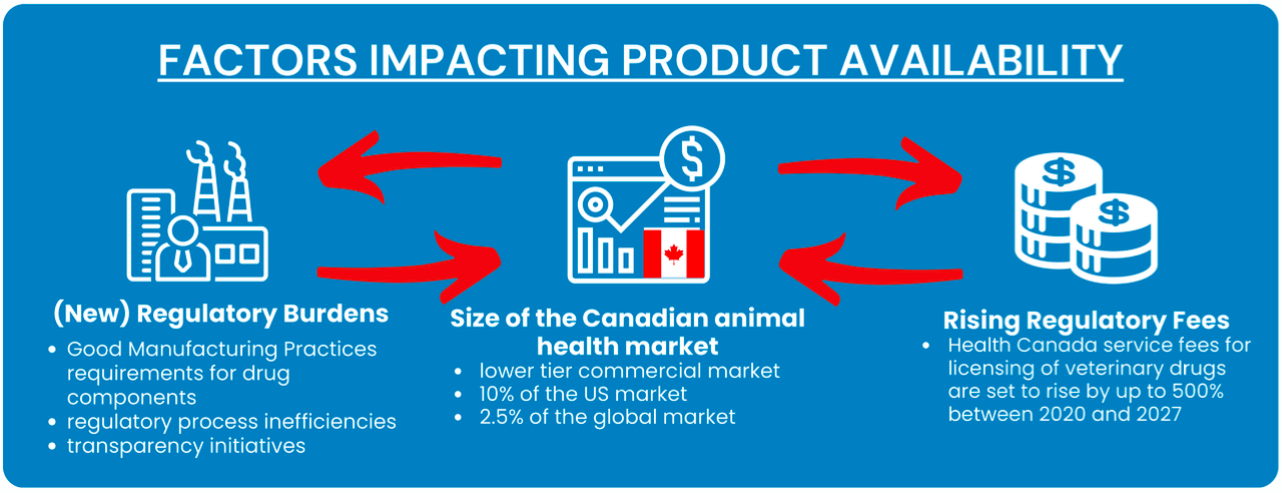
The negative impact of declining access to veterinary medicines in the Canadian market is evident in various aspects of the animal health industry. The shortage of licensed veterinary drugs is affecting animal welfare, the quality of veterinary medicine, and the Canadian livestock industries' overall sustainability and competitiveness. Veterinarians and producers must resort to alternative strategies, such as using compounded products, off-label drug use, own-use importation, and online purchases from other countries to access products not available in Canada. However, these strategies come with severe risks to animal health, environmental safety, and food safety, potentially leading to significant implications for trade and the closure of international borders to Canadian livestock exports.

The availability of veterinary medicines is essential for sustainable food production, as animal health products play a critical role in ensuring the safety and quality of food. The well-being of animals directly impacts human health and the planet's overall health. To address these challenges, the Canadian government should consider amending the Food and Drug Act to allow recognition of foreign decisions made by trusted regulatory authorities in other jurisdictions for Manufacturing, Quality, and Clinical Efficacy Reviews related to the authorization of veterinary drugs. By adopting such a measure, the regulatory process can be streamlined, and the cost-efficiency can be improved, making it easier for companies to access the Canadian market based on approvals and reviews already completed in other trusted jurisdictions, such as the European Union and the United States. This step would encourage more investment in bringing new and innovative products to the Canadian market, promoting the growth and sustainability of the Canadian pulse industry while ensuring the

availability of essential veterinary medicines for animal health and food safety.

Recommendation 3: Drug Establishment License (DEL) fee

In 2017, regulatory changes to improve oversight of veterinary medicines increased Good Manufacturing Practice (GMP) requirements for Active Pharmaceutical Ingredients (APIs).



However, these changes inadvertently put the availability of veterinary drugs in Canada at risk without significantly improving safety or quality. They have added new regulatory fees and significantly increased costs for drug components, with all foreign API sites now incurring an additional annual charge (Drug Establishment License (DEL) fee, a significant deterrent for veterinary drug producers to enter the Canadian market. In addition, a growing number of API sources cannot meet the new Canadian requirements, particularly for low-risk APIs treated as food ingredients in other markets or where Health Canada needs to recognize GMP evidence considered sufficient by regulators in large markets such as Europe. The mix of rising regulatory fees and new regulatory burdens such as DEL hinder the Canadian animal health market, as well as the health of livestock and pets.

For 2023, an additional CPI increase of 6.9% has resulted in an annual rise in regulatory costs for veterinary medicines of up to 20%. This increase will inevitably trickle down the supply chain to livestock and poultry producers and consumers already faced with drastic increases in the price of food.

COVID-19 has highlighted the importance of drug and vaccine availability in Canada. Animal health, however, was out of the spotlight of direct pandemic response and disruptions of international veterinary supply chains. Consequently, there are increased vulnerabilities in the system, and the need to triage disorders consistently results in veterinary drugs being assigned a lower priority than human drugs, despite the significant risks to animal health and welfare resulting from delays. Suppose animal health quality continues to be affected by these supply chain issues exacerbated by new regulatory burdens. In that case, animal health will decline, hindering the food supply and leaving

Canadians at risk for food insecurity. The ongoing yearly regulatory fee increases and DEL fees are expected to deter sponsors from making the initial investments necessary to bring new and innovative products to the Canadian market, so CAHI recommends abolishing DEL fees for low-risk Active Pharmaceutical Ingredients.

Conclusion

Adopting CAHI's three recommendations is crucial to address the declining access to veterinary medicines in Canada. Amending regulatory fees to ensure competitiveness with key trading partners will encourage investment, improving animal health and food safety. Recognizing foreign decisions by trusted regulatory authorities streamlines the process, reducing costs and ensuring a stable supply of essential veterinary medicines. Additionally, abolishing DEL fees for low-risk API will remove barriers for producers, encouraging investment and safeguarding animal health, food security, and the Canadian economy. These measures will enhance animal welfare, food safety, and the competitiveness of the livestock industry while maintaining a globally competitive market for veterinary medicines.