

**Health Canada Service Fee Increases for Animal Health Products:
An Economic Analysis**



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Executive Summary

Health Canada is proposing to increase service fees for the review and maintenance of veterinary drugs, effective April 2019. The fees as initially outlined represent increases in the range of 39 – 500%. This paper examines the unintended consequences that would occur if the fee increases were implemented on Canadian trade interests and on animal health. The proposed fees are not aligned with those of other developed countries such as the U.S., Australia and the E.U. due to major differences in market size. The high fees being proposed for Canada would result in fewer products coming to the Canadian market and will mean companies cease to market minor species and niche products in this country. Small to medium sized enterprises, which are a significant proportion of the Canadian animal health sector, will be challenged to cash flow review of new products and to keep products in the marketplace with the proposed new fees. These factors would negatively impact innovation in Canada and contradict agri-food growth opportunities as outlined in the Barton report (February 2017). Inability to access animal health products could hurt the health status of food animals, result in the substitution of unlicensed product as a means of keeping animals healthy and as a result bring into question the phytosanitary standards of Canadian food animal exports. The proposed fees will have unintended consequences that will hurt the safety of our food supply, our trade with foreign countries and pet owner access to health management tools for their pets. A balanced and holistic view of service fees needs to account for market size and the benefit to Canadians of having access to animal medications to keep animals healthy, to support innovation and for trade in food animals and their products.

Introduction

The purpose of this paper is to provide the relevant context for the proposed changes in Health Canada's service fees for veterinary drugs, review their fit within Canada's trade policies, and to provide an economic analysis from an animal health perspective.

Veterinary, or animal, drugs regulated by Health Canada support Canada's animal health status. They also promote the health and welfare of animals. If the proposed Health Canada service fee increases, ranging from 39 – 500%, for veterinary drugs come into effect there will be negative unintended consequences on both farm and companion animal populations in Canada. There will also be a negative impact on trade in food animals and their products.

The Barton report¹ indicated that the agriculture and food industries represent a significant opportunity for economic growth both domestically and for exports. Canada's role in opening markets through trade agreements and maintaining existing export market access abroad is consistent with the Barton report, and reflects the broader international and foreign policy strategy of the federal government.

A strong and consistent animal health status anchors Canada as a major producer of food animal livestock products, and as a favoured exporter of hogs, cattle, pork and beef. Our exports, in turn, support important upstream and downstream industries.

- According to the Canadian Cattlemen's Association, "*Canada's beef industry contributes \$33 billion worth of sales of goods and services either directly or indirectly to the economy. Every job in the sector yields another 3.56 jobs elsewhere in the economy. For every \$1 of income received by workers and farm owners, another \$2.08 is created elsewhere. Either directly or indirectly through induced income effects, the beef sector generates 228,811 jobs*".
- In 2016, Canadian pork exports amounted to 64 percent of production, and beef exports were 46 percent of production. In a study completed in 2012 by the George Morris Centre, it was estimated that the economic impact of Canadian pork exports was 45,000 jobs at the processing, farming and other supplier levels, \$1.98 billion in wages, salaries and benefits, \$318 million in taxes both income and product related, and Gross Domestic Product contribution valued at \$3.5 billion. Canadian pork exports are up about 5 percent since 2012.

These economic impacts are heavily dependent upon exports. Canada's animal health status – and the health management tools to help maintain it – work together with its natural resource base, and investments in farm production and food processing technology to create the basis for internationally competitive livestock industries. Equally, Canada supports healthy populations of farm and companion animals that support good health and the welfare of Canadian families and the animals they own.

¹ <https://www.budget.gc.ca/aceg-ccce/pdf/key-sectors-secteurs-cles-eng.pdf>

Proposed Service Fee Changes

Health Canada has proposed changes in service fees associated with regulatory reviews for animal drugs and for ongoing quality oversight of licensed product in the marketplace. The proposed fees are being introduced under Ministerial Order outside of the Canada Gazette process for both human and animal drugs. The changes in fees are material and represent very large increases to suppliers of animal health drugs bringing new licensed products to market and maintaining them in the marketplace without consideration for market size and the public good contributions veterinary drugs provide to food safety, human health and the human-animal bond. The proposed fees also do not consider alternative or higher risk options that exist within animal health such as the use of less effective (and sometimes illegal) products to reduce cost, not treating an animal, and euthanasia.

Health Canada implies that the proposed fees appear to be in-line with those applied in the United States (US), Australia and the European Union (EU). The great difficulty with this comparison is that the animal numbers in the US, the EU and Australia are much larger than in Canada, providing for a much larger market served by the drugs. This provides for a much larger population over which to spread costs of product registration and regulatory service fees. In Canada, these costs are concentrated on a much smaller volume of veterinary drugs and animal populations. As increases in these costs are passed along, it creates the strong likelihood of disproportionate increases in prices versus other countries, and that for some products, the relatively small size of the Canadian market, would not warrant the costs of product registration/renewal.

Table 1 below provides an illustration, based on inventories of major livestock species in the US, EU-28, Australia, and New Zealand versus Canada. Inspection of the table immediately reveals that livestock populations in the US and EU, along the corresponding markets for animal pharmaceuticals, are factors of magnitude greater in size than that in Canada. In the livestock commodities in which Australia and New Zealand are export competitors to Canada (notably beef, dairy, and lamb), they support much larger livestock populations than Canada. Moreover, the table identifies the incentives facing drug manufacturers in seeking approvals in Canada for more minor livestock species, as represented by sheep in the table. Canada essentially represents the rounding error on sheep population estimates in any of the EU, Australia, or New Zealand. Clearly the Canadian market could not be a priority market due to its relative size, and additional costs associated with accessing the Canadian market could rationally cause some animal health product suppliers to drop it, at little loss in sales.

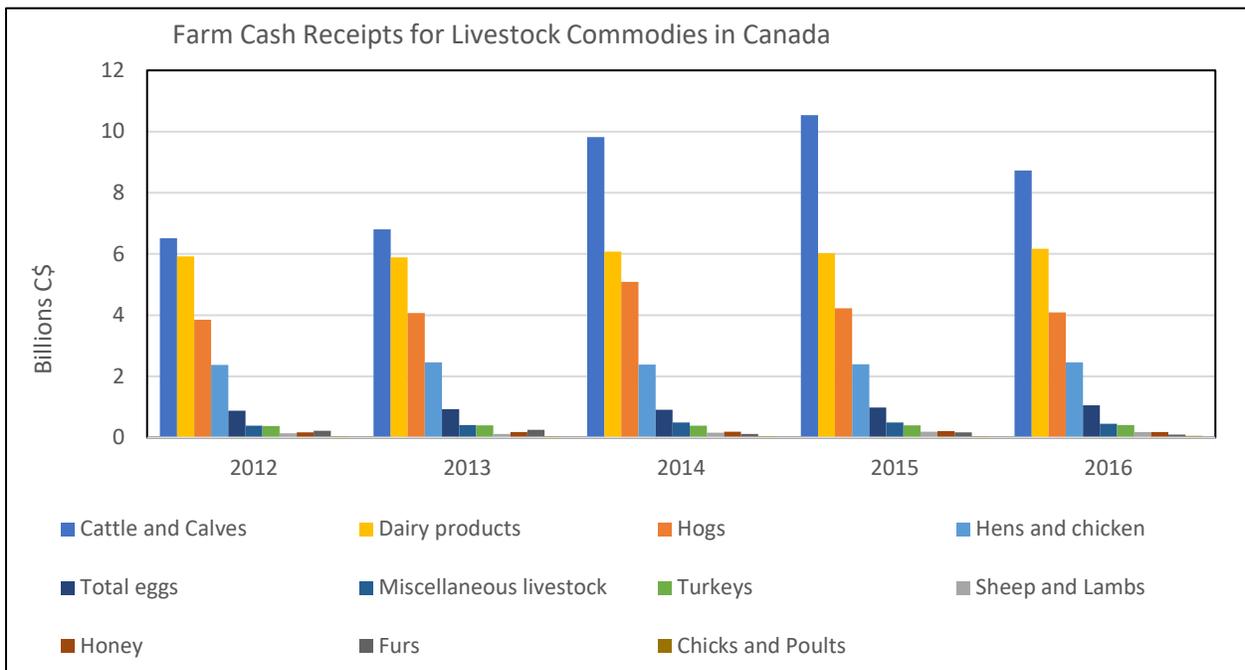
Table 1 Major Livestock Populations- US, EU, Australia, New Zealand, and Canada, 2016

	Total Bovine	Hogs	Sheep	Chickens
	Million Head			
US	91.9	71.5	5.3	1971
EU	90	148.9	98.3	1411
Australia	24.9	2.3	67.54	90
New Zealand	10.15	0.25	27.6	22.7
Canada	12	12.77	0.83	169.6

Source: FAO Stat

Canada exported \$8.4 billion dollars of live animals and meat from bovines (cattle and bison), swine, sheep and lambs and horses (including asses, mules and hinnies) in 2017 to 168 countries around the world in heavy competition with the other major exporters: US, EU, New Zealand and Australia.² In 2016, Canada exported 64 percent of its pork production and 46 percent of beef production. This does not include the prepared meats and other animal products as components in food preparations.

The livestock industry in Canada represents \$23.9 billion in farm cash receipts, 39.6 percent of total farm cash receipts. Only four commodities have farm cash receipts greater than \$2 billion. The remainder of the commodities remain minor in farm cash receipts, although taken together they represent \$2.4 billion. Because they are minor, they will be hit the hardest by the fee increases, potentially losing access to the veterinary drugs currently available, without expectation of new drug approvals.



²Based on export data for HS 01 and HS 02 categories.

Even with these stark differences in livestock populations, Health Canada is proposing that Canada's fees would be "\$\$" (\$75,000 to \$200,000) while Australia is shown as "\$" (less than \$75,000). Moreover, the proposed Health Canada service fees for animal drugs are required upfront, before there is a return on investment, while in Australia the same fees would be collected over a 10 – 15-year period.

These differences have multiple effects on the Canadian livestock industry:

- Veterinary drugs in Canada would be at best regarded as “minor or niche use” by the multinational companies, which would be largely non-remunerative with the new fee levels for introducing new or reformulated drugs into Canada. As a consequence, it could be in the interest of pharmaceutical companies to pull a number of their products registrations in Canada and hold back on registering new products. In other words, the increased fees could result in less revenue from product registrations, along with a reduced number of product registrations in Canada
- Small to medium sized domestic companies could not afford service fees for registering animal drugs or maintaining them in the marketplace.
- The pharmaceutical companies would likely delay registering new or re-formulated drugs, if these are registered at all. Additionally, they would likely set prices well above those charged in the EU, Australia or the US in order to recover the registration fees in Canada, placing the Canadian animal industry at a competitive disadvantage.
- The expectation is that not all drugs currently available for veterinary use in Canada would survive the annual renewal fees as they are withdrawn by pharmaceutical companies due to cost. This in turn would limit access to drugs in Canada's livestock industry, at best, to only the most widely used products for the most numerous animal species (e.g. hogs, cattle, chickens). At the higher licensing fees, Canadian registrations likely would not be sought for the full range of species to which products can be applied, which could be cost justified in other jurisdictions.
- In the absence of accessibility to licensed veterinary drugs, some animal owners and veterinarians will turn to unlicensed drugs in the interest of animal health and welfare.
- These factors would also have negative ramifications for innovation in Canada and on both domestic and multinational veterinary drug companies operating in Canada.

Annual renewal fees increase by 37 percent under the proposed fee structure for Canada, which includes claims for bovines, hogs, chickens, and turkeys. For a range of new drug submissions, the increase is 500 percent by year 2. One can expect that many minor use and niche drugs will disappear from the Canadian market including products which are already licensed for species such as sheep, goats and farmed fish.

For approval of new therapeutics or expansion of coverage to other species, the cost increases are uniformly 500 percent by the second year of the fee implementation. This means that access to new products will face much greater costs for the Canadian animal industry, leading to greater difficulty in staying competitive with the animal industries in other countries. It also means that

new products for minor species and niche uses are unlikely to be pursued by drug manufacturers in such a small market.

Proposed Service Fees for Maintenance of Animal Drugs

Table 2 below provides a summary of proposed fees for the maintenance of an existing animal health product (not a new product registration). As a simple average across the categories of licence review, the overall proposed fee increases average 169 percent. Within the portfolio of categories, some fees will actually decrease; but the dominant character of the proposal is for very large increases in fees. Moreover, the licence fees apply for each species registered - for animal health products often apply to multiple species. In effect, a single animal health product with broad application could face these fees in multiples in direct proportion to the number of species for which approvals are sought. This differs greatly from the human health sector which only deals with one species.

Table 2 Proposed Increases in Licence Fees for Animal Health Products

Name of Fee	Description	Current Fee (average)	New Fee	Change (percent)
Annual Licence Review	Applications for new and renewal of licences.			
Sterile Fabricator		\$39,125	\$41,114	5.1
Non-Sterile Fabricator		\$24,156	\$30,481	26.2
Packager / Labeller		\$14,055	\$5,942	-57.7
Importer		\$24,202	\$31,745	31.2
Distributor		\$10,588	\$16,202	53.0
Wholesaler		\$3,721	\$9,851	164.7
Tester		\$1,928	\$27,109	1,306.1
Foreign Site (each)		\$1,715	\$900	-47.5
		\$119,490	\$163,344	36.7
Average Change				168.6

Source: Fee proposal for drugs and medical devices (for consultation) https://www.canada.ca/en/health-canada/programs/consultation-fee-proposal-drugs-medical-devices/drug-medical-device-fee-change-proposal.html#a3_8_3

High Animal Health Status in Canada – Importance to Trade

Animal health status is an amalgam of health promotion, therapeutic treatment, and relief from stress. Available data are limited; however, Canada submits annual notifications of disease status for specific diseases under its obligations as a member of the World Animal Health Organization (OIE). These data relate to notifiable diseases and as of 2018, there are 117 animal

diseases, infections and infestations recognized as notifiable by the OIE. Over 100 of these have been notified as absent in Canada.³

Table 3 below provides a summary of diseases of livestock that Canada notified from 2003 to 2015. The data are confirmed cases of individual animals; as such, in the case of poultry diseases (such as avian influenza) the values appear quite high. What is evident from the table is that, while the great majority of livestock diseases are absent in Canada, a number of livestock diseases persist, with remedial or mitigating instruments required to treat animals. Other diseases appear suddenly, create a large number of cases, and then abate quickly with the existing control measures available. Still others generate a small number of positive cases, but trigger border closures by some countries, restricting export market access for Canada. One such example is Bovine Spongiform Encephalopathy (BSE) which impacted Canadian cattle in the mid-2000's. Another is Foot and Mouth Disease, which is notified as absent in Canada.

The data illustrate a diverse situation in which Canada needs its full set of health management tools working together to manage its complex animal health context – veterinary infrastructure, inspection resources, laboratories, vaccines, and pharmaceutical products. In several cases, the diseases listed are viral, or not acutely treated with veterinary drugs; however, the susceptibility to secondary infections is high and these can be treated with currently registered veterinary drugs.

Moreover, the data in Table 3 only relate to OIE notifiable diseases. Other production-limiting diseases can be far more economically damaging and are treated effectively with veterinary drugs. Enteric and respiratory infections in farm animals are common- such as coccidiosis in chicken and pneumonia in cattle, hogs and sheep. Veterinary drugs are the primary (or only) means of effective control for many of these diseases.

Costing Basis for Fee Increases?

Health Canada indicates that “Health Canada’s fees are determined based on the cost of providing service to industry.” It goes on to say that “Irrespective of this, in developing its proposal Health Canada reviewed several international regulatory regimes, which charge fees for their therapeutic product regulatory activities.”

The first statement suggests that the increase in fees is based on a costing model for Health Canada services. With a uniform increase of 500 percent across all new drug therapies for animals, it is difficult to believe that a costing formula would yield identical increases for each of the activities by Health Canada, nor such a round number for the fee increases. However, the second sentence quoted above denies that a costing model was used, or completely ignored; simply comparisons to other countries were the basis for the increases. Even here, the

³ See 2016 Semester 2 Notification

http://www.oie.int/wahis_2/public/wahid.php/Reviewreport/semestrial/review?year=2016&semester=2&wild=0&country=CAN&this_country_code=CAN&detailed=1 Note that the link include diseases of terrestrial animals, poultry, birds, bees, fish, molluscs and amphibians, and include wildlife. Data compiled in Table 3 are for terrestrial livestock, including equine, and poultry. Excludes wildlife, camels. Excludes rabies

Table 3 Livestock Disease Cases Notified by Canada to the OIE

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
Anaplasmosis						1	416	185	19		143	12	
Anthrax	22	9	37	953	158	1350	46	75	8	63		1	
Avian infectious laryngotracheitis					4					10			
Avian chlamydiosis					1								
Bluetongue											4		3
Bovine Leukosis		4											
Bovine Spongiform Encephalopathy	2	1	1	5	3	4	1	1	1				1
Bovine Tuberculosis	3	7		27	1	7			7				
Brucellosis													
Cysticercosis		1	10				2	1			1		1
Echinococcosis/hydatidosis							1			1			
Equine encephalomyelitis		1				17	13	11				29	9
Equine Infectious Anemia	58	69	121	53	64	18	78	23	8	130	113	68	74
Fowl Cholera					4								
Notifiable Avian Influenza		53			540		1300	1				9094	11993
Scrapie	12	1	4	6	3	19	10	31	8	52	233	93	7
Trichinellosis											1		
West Nile Fever					255		8	1		50	59	21	20

Note: includes terrestrial livestock, poultry and equine. Excludes wildlife, camels. Excludes rabies

comparison with Australia clearly shows the proposed new Canadian fee structure lies well above that for Australia. What was missing in the comparisons was the market size differences between Canada and the EU, US, and even Australia, as already noted, along with the long term economic costs for the Canadian economy.

Policy Congruence – or Incongruence

Canada has aggressively pursued trade agreements predicated on competitive livestock industries that can successfully compete in domestic and export markets. Recent examples include the Comprehensive Economic and Trade Agreement (CETA) with the EU and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP). Canada is also engaged in trade negotiations with India and is exploring the feasibility of freer trade discussions with China.

Under CETA, Canada obtained significant tariff-free access for beef and pork – approximately 50,000 tonnes of beef and 80,000 tonnes of pork – and allowed for tariff-free import of cheese from the EU, eventually up to almost 18,000 tonnes. As such, Canada positioned itself with the expectation that it can capitalize on increased pork and beef exports in competition with existing EU suppliers. Existing Canadian beef and pork exports to the EU are relatively small; cost competitiveness will be important to market penetration, with subsequent development of

Canadian brands in the EU. At the same time, increased imports of cheese from the EU will pressure cost competitiveness in the Canadian dairy industry.

Under CPTPP, Canada obtained enhanced access to the Japanese market for beef and pork. Japan is a premium market for meats, requiring the highest of product quality standards, with meticulous attention to animal health and sanitary/phytosanitary standards in countries originating Japanese imports, sometimes right down to the individual processor or farm level. Satisfying these exacting standards and making good on Canada's opportunity in Japan will require the complete suite of available tools to safeguard and promote animal health. At the same time, Canada agreed to phase-in exemption to its beef Tariff Rate Quota for CPTPP countries. This opening of market access to others will further pressure efficiencies and competitiveness in Canadian cattle and beef.

Finally, the red meat segments of livestock in Canada exist in a deeply integrated North American market in hogs/pork and cattle/beef that has developed over almost 30 years. Canada's high animal health status has been a crucial element of success in this environment. Canada is engaged in negotiations toward the renewal of the North American Free Trade Agreement (NAFTA) with its American and Mexican partners, at the request of the US. The outcome of this re-negotiation discussion is uncertain but could involve changes in access to the Canadian market for the US and Mexico, especially in dairy, poultry, and beef. With the outcome and legacy of NAFTA renegotiation still being determined, an important hedge against the uncertainty for Canada is further and ongoing competitiveness improvements in its livestock segments. Veterinary drugs and animal health products as instruments to maintain and improve competitiveness are fundamental to this.

What appears clear from the above is that Canada is continuing in its evolution toward more of an export focus in agri-food, and especially in red meats. This presents the opportunity for Canada to match its agricultural production capacity that greatly exceeds the domestic market with optimal export markets. At the same time, this evolution toward greater reliance on export markets presents increased risks due to disruptions in export market access from animal health events. Access to the full range of animal health management tools, and innovation of new animal health products, are a critical element of mitigating the risk of such market access disruptions.

Canada experienced export market disruption in the BSE crisis in the mid-2000's. Another illustration was developed by the OECD of the potential cost of an outbreak of Foot and Mouth Disease (FMD) on Canada⁴ (Junker et al, 2009). The prospective analysis considered the effect on major importing and exporting countries, and the costs/efficacy of alternative control measures – stamping out the outbreak through culling, regionalization of treatment, and vaccination, as well as combinations of these – and also considered the effect of trade restrictions while the outbreak was being brought under control. The results showed that the FMD outbreak

⁴ Canada notifies FMD as absent; the purpose of the study was to illustrate the potential costs of livestock disease outbreaks and costs of control and disruption in export market access, using Canada as an example

would cost Canada between \$US 794 million and \$US 2 billion due to the trade effects, and that the costs of control could exceed \$US 200 million.

Companion Animals

Access to current and affordable animal health products is a critical aspect of the health of companion animals; moreover, the costs of animal health treatment and maintenance influence individuals' economic access to companion animals. It is estimated that there are 7.6 million dogs and 8.8 million cats in Canada. Of these, 6.4 million dogs and 4.8 million cats are estimated to have at least annual visits to a veterinarian⁵. It has been estimated that horses number over 960,000 (2010)⁶ in Canada when Statistics Canada estimates of livestock on farms are extended to include horses resident at riding stables and event centres. Many households, across economic and social strata, have cats and dogs as pets and are owners of horses or other animals for recreational, competitive, or personal therapeutic purposes.

Restricted access to animal health products – either due to lack of renewal of existing products, new products not submitted for registration, or products registered but with the increased costs of registration passed through to retail prices – end up limiting the access of Canadians to companion animals. Alternatively, impeded access to animal health products will induce pain and suffering to some companion animals, and increase the veterinary procedures required to address acute ailments that could otherwise have been prevented, mitigated or treated with veterinary drugs. It can be anticipated that the difficult decision of whether to euthanize suffering companion animals will become increasingly common as access to effective treatments is constrained.

Conclusion

The fee increases proposed by Health Canada represent a significant blow to maintaining and expanding Canada's veterinary drugs at home and abroad. Access to up-to-date animal health products will become significantly more difficult because of the proposed fee increases. Annual renewals will decline, particularly for the minor animal species and niche uses, and requests for approvals for new therapeutics will decrease. This will leave Canada's animal-based industries in a less competitive position domestically and internationally, with these adverse effects increasing over time. It will also leave the many households with dogs and cats, and horse enthusiasts, with an increasingly difficult challenge of keeping their animals healthy and in good welfare.

Canada's farm animals and their products are critically important to the agri-food industry, representing nearly 40 percent of farm cash receipts, and over \$8 billion of exports of live animals and meats, not including prepared meats or products containing animal products. The industry is a major source of jobs, investment and potential export growth under recent and prospective trade agreements.

The Health Canada fee increases appear to be sharply contrary to Canada's international economic strategy. The excessive and immediate increases in fees ignore the impacts on

⁵ Estimates from survey conducted by Kynetec (2016) on behalf of the Canadian Animal Health Institute

⁶ Study conducted by Strategic Equine, Inc., 2010

Canada's animal industry, with no consideration of economic measures regarding market size in comparing fees across countries, and their effects on trade and competitiveness, and are at odds with Canada's strategic international trade and foreign policy objectives.

It is in no one's interest to weaken Canada's animal health status, but the proposed service fee increases amount to an administrative change with far reaching and unintended consequences that will logically create this effect. It will weaken Canada's agriculture, the safety of Canadian food products and impede trade. Its costs will create inequities among households in terms of economic access to companion animals; for some, it will put pets and animal-based recreation out of reach which is at odds with the benefits of the human-animal bond on owner physical and mental health.

A balanced and holistic view of service fees needs to account for their linkages to animal health product availability and innovation in new products, Canada's animal health status, the cost impacts the proposed fees impose on users.

References

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