GLOBAL BENCHMARKING SURVEY 2020

Benchmarking the competitiveness of the global animal health industry

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Global Benchmarking Survey 2020
Report for Canada

1. Executive summary

The HealthforAnimals Global Benchmarking Survey is run every 5 years and has now grown to include 12 countries in the 2020 survey. Its purpose is to examine the interactions between industry and regulatory systems for veterinary medicinal products, and particularly the impact of regulations on the animal health industry's ability to access markets, be innovative, continue to commercialize existing products and be competitive.

This is the fourth report which has been generated for Canada, following earlier reports issued in 2006, 2011 and 2015. It summarizes the data from 14 companies operating in Canada, examining key trends to provide a basis for comparisons with the other key markets surveyed.

This report summarizes consensus responses to a standardised questionnaire in Q4 2019, which were discussed and agreed upon in a workshop teleconference with participating companies. The key points emerging from the workshop discussions are an integral part of the report, which follows the structure of the standardised questionnaire, with 6 separate sections.

Key Conclusions

Section B – Impact of the Canadian regulatory environment on ability to innovate

The regulatory environment can be both an enabler and a disabler of innovation. In the veterinary medicines sector, there is a continual tension between the small size of the Canadian market and the need to provide the necessary level of oversight for the protection of public health and animal health. As a result, the extent and cost of data requirements, determining the level of acceptable risk for veterinary medicines and benefit-risk approaches to regulation are critical factors to how successfully companies can engage in innovation. Data requirements must therefore be finely tuned to appropriately reflect benefits and risks, as well as the unique characteristics of the veterinary medicines sector.

Despite several ongoing challenges to innovation in the Canadian regulatory environment, participants in the benchmarking survey workshop teleconference indicated an overall positive assessment of that environment.

The top factors influencing innovation in Canada are a need for modernisation of the existing regulatory framework, lack of transparency, small size of market segments and lack of financial resources.

In 2019, companies reported significant increases in mandatory defensive research and development (MD-R&D) costs as a result of new regulatory requirements, regulatory changes outpacing updates to related guidance documents, and insufficient harmonization with the US and the European Union. It is important to note that increasing costs of product licence renewals related to new regulatory requirements may lead to products not being maintained on the Canadian market beyond the renewal date. Additional drivers for increased costs of product maintenance are surveillance requirements for antimicrobial resistance and use, and environmental risk assessments.

On the positive side, Canadian companies did report a slight decrease in time required for the product registration step for pharmaceuticals for major food and companion animals since 2015. However, significant issues with registration of EU-approved biologics, and problems with medicated feed additives and products for minor uses and minor species are persistent. Challenges related to the development of products for minor species are further exacerbated by a lack of incentives related to data protection/market exclusivity in Canada.

Section C – Commercialisation of existing product

The top three most important regulatory factors relevant to the exploitation of existing products by the animal health industry in Canada are reported as being new GMP requirements for APIs, the regulatory framework for maintenance/extensions of licences, and pressure from competitors (including parallel imports and generics).

The most important and worrying effect that government regulations in Canada have on business in the Canadian animal health industry is that they are leading to the removal of profitable products from the Canadian market as a result of three main regulatory initiatives:

1) The introduction of new GMP requirements for APIs;
2) The removal of growth promotion claims from labels of medically important antibiotics – while this regulatory change was widely supported by industry, the additional data required to add new (non-growth promotion) claims for old products have made it difficult to keep these older products on the market; and
3) New Health Canada service fee increases, which are coming into force in 2020 and are expected to drive the costs of maintaining products on the market up even further to unsustainable levels.

Section D – Regulatory predictability and quality

Canadian companies participating in the 2020 survey reported relatively positive perceptions of the predictability and quality of Canadian regulatory procedures with respect to veterinary drugs and biologics. Perceptions of procedures related to pesticides scored somewhat less positively, while those related to medicated feed additives were characterized as being unpredictable and of poor quality.

Suggested improvements to increase the predictability and quality of regulatory procedures included provision of better guidance and development of closer alignment with both the US and EU for both drugs and biologic products; improving clarity and consistency across all regulatory agencies; development of a better understanding of veterinary uses for regulation of pesticides; and development of a strategy to deal with the significant backlog of medicated feed additive submissions which makes the regulatory process for these products so unpredictable.

Section E – Regulatory trends

Some significant beneficial changes have occurred within the Canadian regulatory framework since the previous survey in 2015, including the implementation of shared and joint reviews and a movement toward electronic submissions for drugs, and pharmacovigilance reporting for both drugs and biologics.

However, there still remains a long list of areas where industry expectations for change have not been met. Modernization in program delivery continues to lag (*e.g.* use of foreign reviews and decisions,

secure modern gateways for e-submissions, etc.); the minor use minor species (MUMS) program continues to lack clarity; fees remain disproportionate to the small size of the Canadian market and so are likely to lead to removal of products; and the lack of clear, updated guidance documents continue to act as impediments to the Canadian animal health industry.

Developments that have caused the most problems are new GMP requirements for APIs, additional service fee increases and the requirement for a unique Canadian Drug Master File.

Canadian regulatory frameworks were also found to have had a significant influence on Canadian companies' major business decisions with respect to investing in production outside of Canada, increasing product ranges in Canada, restricting (geographic) market focus in Canada, reducing coverage of species or indications in Canada, and focusing on new technologies in Canada.

Section F – Hopes and expectations for the next 5 years

The topmost helpful trends identified were the increasing trend to move from a zero-risk approach to a benefit-risk assessment, and acceptance of JECFA agreements for residues of non-contentious molecules. The use of foreign regulatory decisions in the Canadian review process has a positive impact on companies' ability to innovate.

The most unhelpful trends identified were increasing transparency with respect to data disclosure, the trend towards wider participation in the regulatory process (including public comment) and increasing requirements for post-marketing surveillance and pharmacovigilance. In addition, while companies operating in Canada appreciate the benefits of increasing globalisation of post-marketing surveillance outcomes, compliance with new Health Canada requirements for the reporting of adverse events occurring globally also requires significant time and resources.

It is thus not surprising that the changes that Canadian industry still wants to see include a continued and increased move to benefit-risk assessment approaches, better alignment and harmonization with EU requirements and VICH guidelines, and improved timeliness of reviews facilitated by use of foreign decisions and triaging of foreign site assessments.

It is also worth noting that while COVID-19 had not yet arrived when the data for this GBS2020 report was collected in Q4 of 2019, the impacts of the pandemic on regulatory frameworks, including a decreased ability for in-person foreign site inspections, implementation of widespread remote work arrangements for government workers and a concurrent acceleration of the move to electronic submissions, are likely to have far-reaching consequences for overall regulatory review processes, and may serve to accelerate the modernization of both national frameworks and processes.

Section G – Regulatory cooperation and special product categories

The Canadian Veterinary Drugs Directorate (VDD) engages in joint and parallel reviews with other regulatory authorities, and in general, this process has had a positive impact on innovation in Canada. Joint and parallel reviews have helped to ensure market availability of products in Canada at the same time as other developed jurisdictions.

While special product categories do exist in Canada, there are ongoing challenges with respect to inconsistencies between Canadian requirements for these categories and those of other jurisdictions, as well as a lack of flexibility to allow conditional approvals in Canada, as is the case in other jurisdictions.

Summary and recommendations

Regulatory environments evolve slowly, and the Canadian environment is no exception. As a result, many of the issues, hopes and expectations identified in previous surveys are carried forward in this one. Yet the overall perception of Canadian companies of the regulatory environment within which they operate is a positive one and appears to represent an improvement over perceptions reported in previous surveys.

At the same time, many challenges continue, not least of which are ongoing increases in the costs of not only product development but also product maintenance in Canada. A need for further modernization of the Canadian regulatory framework is another common thread that emerges repeatedly throughout this report. Such a modernization would result in a predictable system that manages risk and supports continued regulatory harmonization/convergence, while remaining sufficiently nimble to support innovation and address changing needs within veterinary medicine.

Key recommendations

- Continue the drive for greater regulatory cooperation and alignment between trusted regulators, as well as international harmonisation and convergence
- Build on efforts to make regulatory processes and procedures more transparent, timely and efficient
- Address the issue of high expenditures on mandatory defensive R&D, and proposed increases to service fees for veterinary drugs for 2020-2027
- Ensure risk assessments related to environmental safety and antimicrobial resistance are appropriate and proportionate to the veterinary sector
- Continue to build more opportunities for dialogue between industry, regulators and other key stakeholders in order to work together for the most successful outcomes
- Continued commitment to regulatory cooperation and alignment

2. Introduction and background

The purpose of the HealthforAnimals Global Benchmarking Survey is to examine the interactions between industry and regulatory systems, particularly the impact of regulations on the animal health industry's ability to be innovative and competitive. This includes the ability to bring new products to the market, as well as to maintain existing products on the market, and thus reflects the impact regulations have on the availability of veterinary medicinal products.

Initially, the global survey benchmarked only the European and USA regulatory systems but has since evolved and grown to include 12 countries in the 2020 survey (see Box 1).

Box 1

The evolution of the Global Benchmarking Survey

1. 1996: Europe, USA
2. 2001: Europe, USA
3. 2006: Europe, USA, Japan, Australia, Canada,
4. 2011: Europe, USA, Japan, Australia, Canada,
5. 2015: Europe, USA, Japan, Australia, Canada, China, Brazil
6. 2020: Europe, USA, Japan, Australia, Canada, China, Brazil, India, South Africa, Russia, Mexico

With the cooperation and involvement of the HealthforAnimals member national associations, the survey is run every 5 years. The purpose thus expands beyond simple benchmarking, to include monitoring of trends and identifying emerging issues in the regulatory environment that may have an impact on competitiveness, ability to do business and availability of medicines. The survey is also a useful tool to gain insight into industry expectations over the next 2-3 years in response to current regulatory dynamics, and to provide information that allows for the development of clear action plans for meeting any identified challenges.

The outcome of this survey provides a wealth of information to support informed policy decisions in the continual search for best regulatory practice and opportunities for improvement.

This report summarizes the data from **14 companies operating in Canada** (11 multinational companies (MNC) and 3 local companies).

List of CAHI member companies participating in the 2020 survey:

1. *Bayer Animal Health (MNC)*
2. *Bimeda MTC (MNC)*
3. *Boehringer-Ingelheim AH Canada (MNC)*
4. *Ceva Animal Health Canada (MNC)*
5. *Dechra Development LLC (MNC)*
6. *Elanco Canada Ltd. (MNC)*
7. *Merck Animal Health (MNC)*
8. *Phibro Animal Health Corporation (MNC)*
9. *Trouw Nutrition Canada (MNC)*
10. *Vetoquinol N.-A. Inc. (MNC)*
11. *Zoetis Canada (MNC)*
12. *Bioagrimix (Local company)*
13. *Grey Wolf Animal Health (Local company)*
14. *Paul Dick and Associates (Consulting Firm)*

3. Outline methodology

The previous Benchmarking Survey questionnaire from 2015 was updated to reflect the requirements for the 2020 survey, including: retention of core questions important for global benchmarking and long-term trend analysis; removal of less useful questions; addition of new questions reflecting known new developments within regulatory systems; and addition of selected 'local' questions of importance to an individual country for local versions of the questionnaires.

The survey was divided into two parts. Part 1 covered financial data and product development costs and was sent to the headquarters of each company (so regional offices were not involved). Part 2 covered the regulatory environment and its impact on innovation and competitiveness. The Part 2 questionnaire was adapted to the situation in each of the 11 surveyed markets and was completed by the country offices of companies active in those markets.

The national associations were responsible for requesting their membership to complete the questionnaires, to collect and collate the results using a standard template, and to organise a local 1-day workshop with those companies participating in the survey. At the workshop, an aggregated summary of the data for each question was to be presented and discussed in order to explore and record different views and the local context important for an understanding of the reasons behind a particular outcome.

The assimilated questionnaire data and the workshop 'narrative' explaining the findings was to form the basis of each country report. The report structure follows the list of questions, which are used as sub-headings. These questions are presented at the beginning of each section in a box below each sub-heading.

The GBS2020 survey covers 11 markets: Europe, United States of America, Japan, Canada, Australia, China, Brazil, India, Russia, South Africa and Mexico.

Final output: The country reports and a global overview report will be published on the HealthforAnimals website: **https://healthforanimals.org/global-benchmarking.html**

Details for Canada

In Canada, the Canadian Animal Health Institute convened a workshop teleconference call on October 31st, 2019, with participation from **14 member companies**, during which responses to the questionnaire were discussed and agreed upon with the group.

For more information on the Canadian Animal Health Institute membership please visit: https://www.cahi-icsa.ca/

4. The findings for Canada

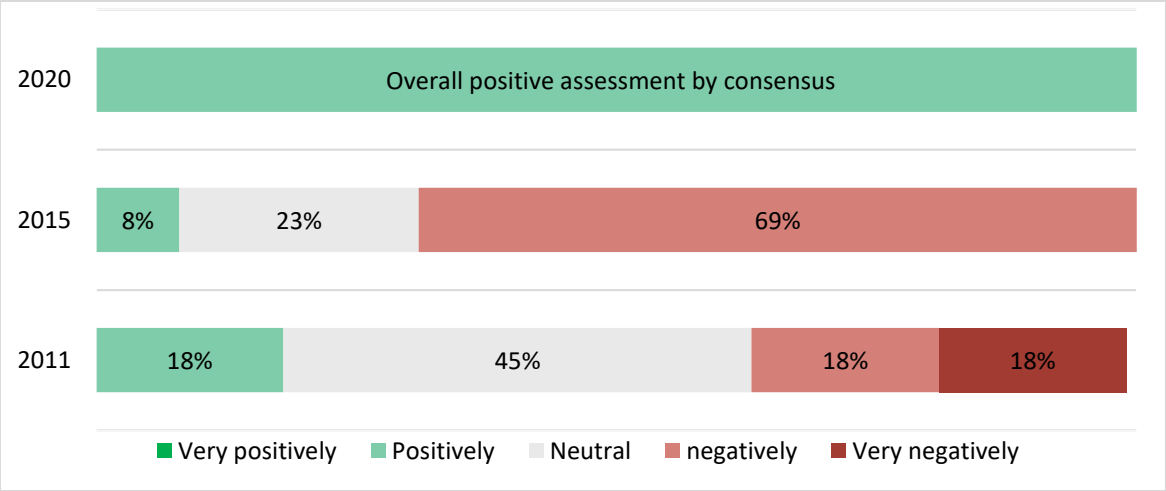
Section B – IMPACT OF REGULATIONS ON INNOVATION

Impact of the Canadian regulatory environment on ability to innovate

How does the regulatory environment in Canada impact your ability to innovate?

Over the past decade, there has been a significant shift in industry perceptions of the impact of the regulatory environment in Canada on the ability of companies to innovate. Earlier surveys in 2011 and 2015 found that the majority of companies participating in those surveys viewed the Canadian regulatory environment negatively, or at best neutrally. By contrast, participants in the benchmarking survey workshop teleconference at the end of 2019 indicated an overall positive assessment of the regulatory environment's impact on their ability to innovate.

Figure 1: Impact of the Canadian regulatory environment on ability to innovate



Factors relevant to innovation in the animal health industry

Below is a list of factors relevant to innovation in the animal health industry. Which of these, if any, are significant for innovation in your business in Canada? Rank from 1 (highest significance) to 11.

Table 1 below shows the factors relevant to innovation in the animal health industry in Canada, ranked from highest (1) to lowest (12) priority.

The highest ranked factor is a need for further modernization of the Canadian regulatory framework. This particularly applies to Good Manufacturing Practices (GMP) requirements for Active Pharmaceutical Ingredients (APIs), recognition of minor species/minor uses, as well as the use of foreign reviews and foreign decisions to support the availability of veterinary products in Canada. There are important differences with respect to the management of levels of risk related to antimicrobial use in veterinary medicine versus human medicine, and the regulatory framework would benefit from an acknowledgement of these differences and their inclusion in the considerations informing benefit-risk assessments in Canada.

The next most impactful factors for innovation are transparency, small size of market segments, and lack of availability of financial resources. A lack of availability of up-to-date guidelines on current regulatory expectations with respect to technical requirements involving GMP for APIs, Post Notice of Compliance (NOC) requirements, and requirements for antimicrobials for production animals were all noted under the transparency factor.

With respect to small market segments and availability of financial resources, companies have sales thresholds which need to be considered when bringing a product to the Canadian market. When regulatory authorisation and product maintenance costs exceed sales thresholds, this creates an impediment not only to innovation but also the availability of medicines on the Canadian market.

Negative consumer attitudes towards veterinary medicines, ranked as the 7th most important factor relevant to innovation, are particularly focused on antimicrobial use in production animals, and are reflected in initiatives such as the Chicken Farmers of Canada's Antimicrobial Use Reduction Strategy, which includes limiting the preventive use of certain antimicrobials, and the province of Quebec's decision to limit the use of Category I antimicrobials in animal production.

Table 1: Ranking of factors relevant to innovation

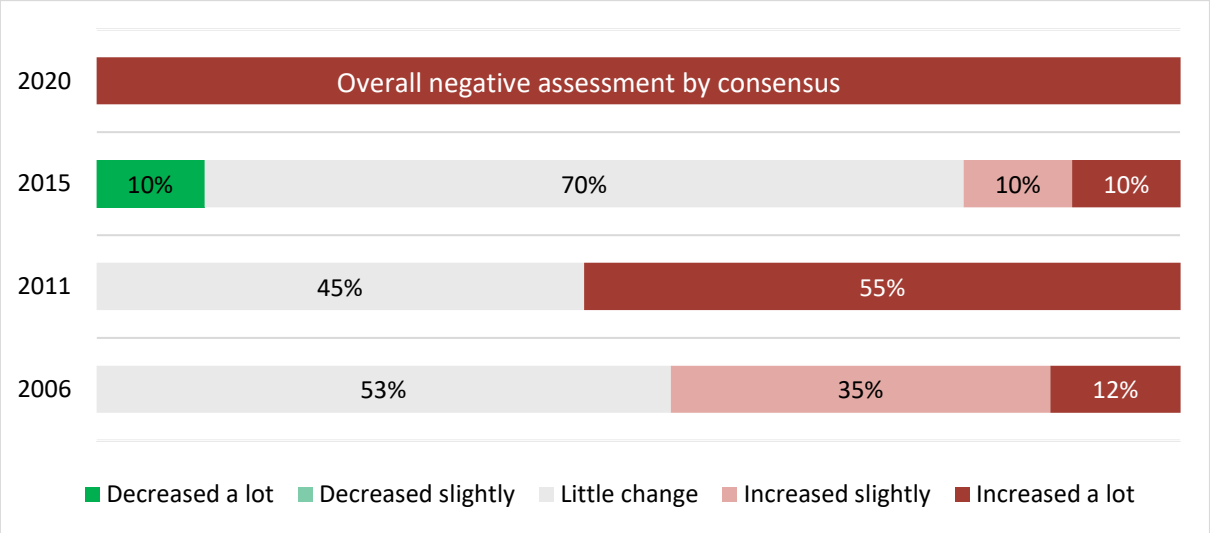
Factors relevant to innovation	Importance Rank Score
The Canadian regulatory framework's need for modernization	1
Lack of transparency and updated guidelines on current expectations	2
Small size of market segments	3
Lack of availability of financial resources	4
Recognition of novel therapies/submission requirements	5
Inadequate intellectual property protection (for patents or commercial data)	6
Negative consumer attitudes	7
Lack of access to specialist biotechnology companies	8
Lack of skilled staff	9
Poor technology transfer mechanisms between academia and business	10
Internal company organizational or cultural barriers	11
Closure of the Canadian and/or other geographic markets for certain products	12
Other: Canada requiring greater documentation than other developed country regulatory agencies	12

Expenditure on mandatory defensive R&D

Which of the following statements best indicates how your expenditure on MANDATORY DEFENSIVE R&D in Canada has changed since 2015?

While the actual reported increase in Mandatory Defensive R&D was minimal from 2006 to 2011, the decade that followed showed a roller coaster of ups and downs. From 2011 to 2015, some decreases occurred, and increases were slowed. Unfortunately, the last five years have shown a return to major increases.

Figure 2: Changes in expenditure on mandatory defensive R&D since 2011



Factors causing the change in expenditure on mandatory defensive R&D

The factors reported as causing an increase in expenditure on mandatory defensive R&D (MD-R&D) are listed in Table 2 below, and have been grouped into the following three main areas:

- Regulatory requirements
- Insufficient harmonization with US and EU requirements
- Regulatory changes outpacing updates to related guidance documents

It should also be noted that the increased cost of renewals may lead to products not being maintained on the Canadian market beyond the renewal date, and surveillance requirements for antimicrobial resistance and use, and environmental risk assessments are strong drivers of increased costs of product maintenance.

Table 2: Factors causing the change in expenditure on mandatory defensive R&D

Factors causing an increase in expenditure on mandatory defensive R&D
• **Regulatory requirements:** - New good manufacturing practices (GMP) requirements for active pharmaceutical ingredients (APIs) make it hard to find suppliers and increase the time required to bring product to market (*e.g.* impurity profiles). In addition, the new requirements raise concerns around our ability to manage animal welfare, as well as public health, into the future. For example, no coccidiostat has ever been licensed in Canada for dogs. Veterinarians used to have product compounded, but now compounders are also having challenges sourcing GMP APIs for small market use, and there is no canine coccidiostat product available in Canada. - Canadian specific requirements for drug master files (DMF), which can lead to sales being stopped.
• **Lack of alignment of Canadian requirements with those of the US and the European Union:** - Canadian generic veterinary drug requirements are not aligned with the USA and EU in the following areas: o Non-aqueous solutions are not eligible for waiver of bioequivalence studies o Scientific justification is required for selection of any method (such as aseptic processing) other than terminal steam sterilization to ensure sterility of drug product o Added burden of requiring 3 batches for release rather than the 2 required by the US. o Biowaiver of non-Bioequivalence (BE) strengths related to F2 criteria do not match. The USA's FDA allows that if F2 criteria for similarity do not match between strengths of the proposed generic and the same can be demonstrated with the innovator product, a biowaiver can still be granted for the other strengths. If additional BE studies are needed to satisfy additional requirements, then some generics will only become registered products in the USA, and not Canada. - Impact of proposed Environmental Risk Assessment regulatory amendments where there are concerns about alignment, or lack thereof, with the USA and EU
• **Regulatory changes outpacing updates to related guidance documents:** - Applicable regulations have been updated but the related guidance documents have not kept up.

TIME to gain registration for a major new product in Canada

Please state the AVERAGE LENGTH OF TIME it takes you to gain registration for a major new product in Canada, from submission of the marketing authorisation dossier to first-market product approval.

In 2020, the average length of the registration step for major pharmaceutical products for major food animals and companion animals is reported to be shorter by approximately 6 months and 4 months respectively, continuing a positive trend since 2011.

It should be noted, however, that the pharmaceutical program still requires modernization, and significant delays can result if a company does not engage in a pre-submission meeting at the beginning of the registration step. In addition, the process for Regulatory Cooperation Council submissions is not well defined and the efficiency of this review process is beginning to erode due to delays.

US-approved biologicals continue to benefit from a fast registration procedure and no significant change in duration of the registration step for major food and companion animals was reported (see Table 3 and Figure 3 below).

By contrast, significant problems were identified with respect to the registration of EU-approved biologicals for major food and companion animals (see Figure 3), medicated feed additives for major food animals, and pharmaceutical products for minor species (see Figure 4).

With respect to EU-approved vaccines, while the Canadian Centre for Veterinary Biologics (CCVB) is aligned with the US market and meeting service standards for registration of US-approved vaccines, this is not the case for EU registered veterinary vaccines. This lack of alignment has resulted in products either being delayed or not coming to the Canadian market at all. This has consequences for animal health and welfare in Canada, as the CFIA's CCVB Single Entry Program only allows the importation of a specific lot of vaccine following a request from a veterinarian, even if the vaccine is requested frequently by vets.

For pesticides, no significant change in duration of the registration step for major food and companion animals was reported.

As of 2019, registration of medicated feed additives was significantly delayed due to a 1-year backlog of submissions with the CFIA.

Finally, data for the registration of products for minor species was difficult to quantify categorically as a result of a lack clarity for the minor uses/minor species (MUMS) program in Canada and the fact that requests are dealt with on a case-by-case basis. The data in Table 3 for minor species biologicals relates to piscine vaccines developed for the Canadian market, which typically had a 6-month registration step timeframe.

Furthermore, the cost of Health Canada's Pest Regulatory Management Agency (PMRA)'s service fees does not support MUMS registrations for pesticides, and this program is non-competitive, with fees being very high relative to the market size. Additionally, the PMRA lacks expertise in assessing veterinary pesticides because of its crop/plant-based focus. This area also requires modernization relative to fees, service standards and requirements.

Table 3: Time to gain registration for a major new product in Canada

		Length of time - years			
		Average 2011	Average 2015	Consensus in 2020	Range 2020
Major Food Animals	Pharmaceuticals	2.6	2.1	1.5	1-2
	Biologicals (US approved)	1.4	0.5	0.5	0.5
	Biologicals (EU approved)			2	**1-3**
	Medicated Feed Additives	--	--	1	**1yr backlog**
	Pesticides	2.5	2.4	2.5	2-3
Companion Animals	Pharmaceuticals	2.3	1.9	1.5	1-2
	Biologicals (US approved)	1.2	0.6	0.5	0.5
	Biologicals (EU approved)			2	**1-3**
	Medicated Feed Additives	--	--	--	N/A
	Pesticides	1.7	2.5	2.5	2-3
Minor species	Pharmaceuticals	2.0	1.5	3.5	**1-7**
	Biologicals	--	0.4	0.5	--
	Pesticides	--	1.5	--	--

Figure 3: Average Length of Time for Major New Biologicals Registration (2011 – 2020)

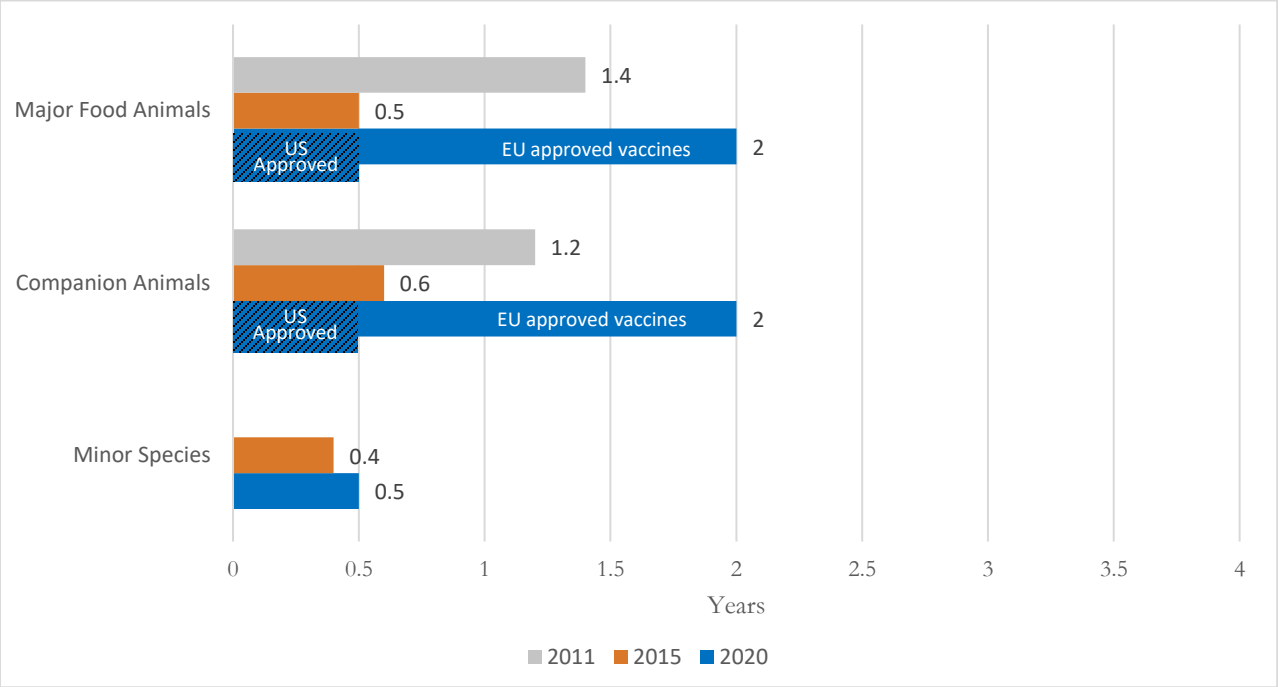
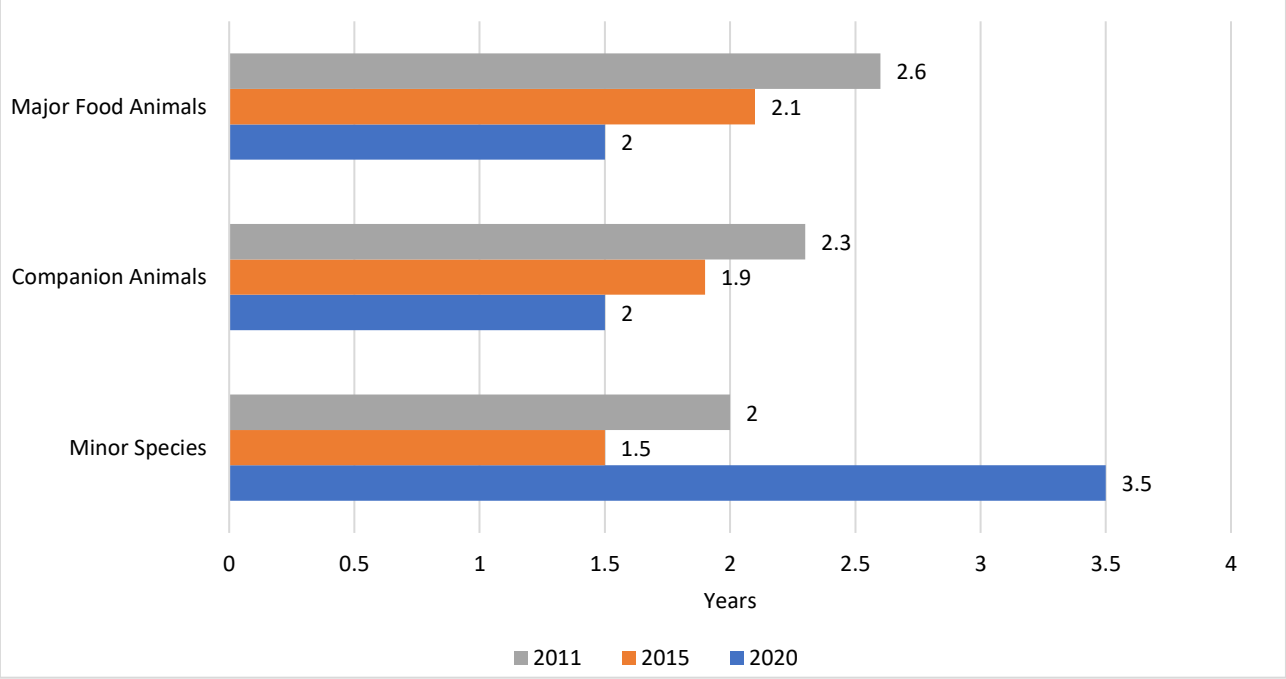


Figure 4: Average Length of Time for Major New Pharmaceuticals Registration (2011-2020)



Impact of Regulations on TIME to develop a major new PHARMACEUTICAL product

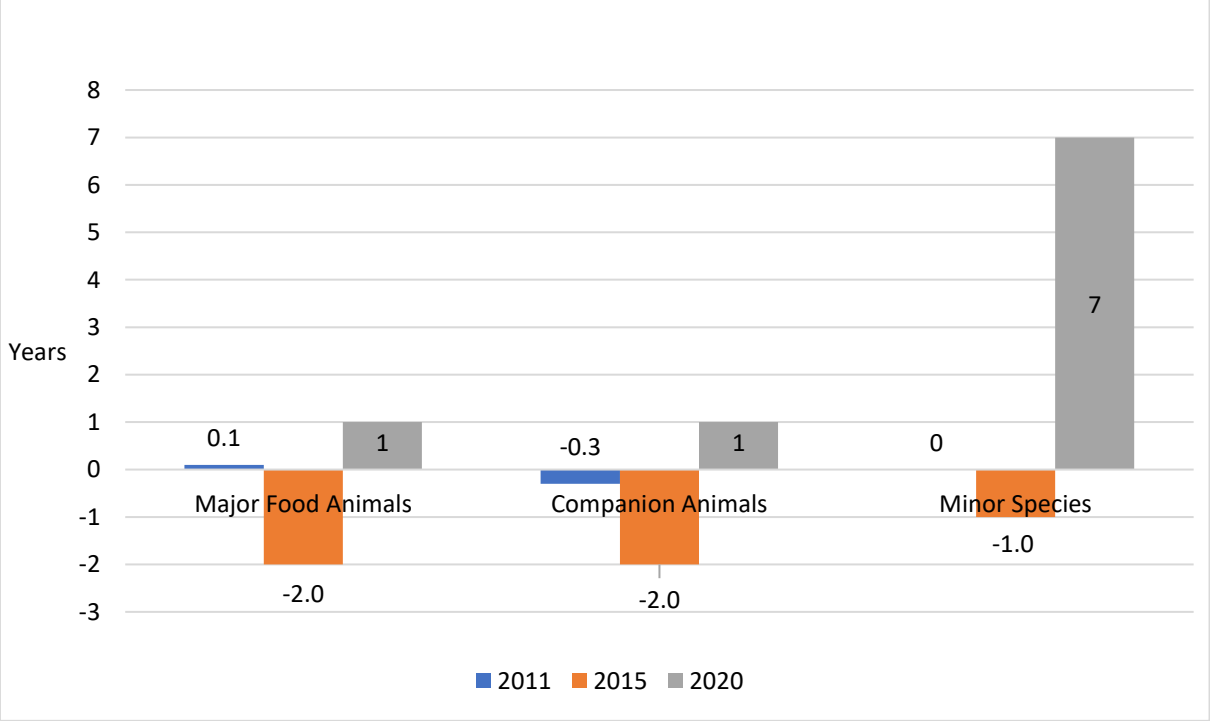
Have REGULATORY FACTORS caused a change in the AVERAGE LENGTH OF TIME it takes you to develop a major new pharmaceutical product in Canada (from initial research to final market authorisation), compared to 2015?

Since 2015, the average time required to develop a major new product for major food or companion animals has **increased by 1 year**, mainly as a result of chemistry and manufacturing requirements, where Canada is not aligned with other developed countries. This results in companies having to spend additional time and resources on aspects such as the product impurity profile, quality assurance signed document requirements, microbial safety, GMP for APIs and a 250-day foreign site review timeframe, along with executed batch records and a Canadian requirement for endotoxin testing.

With respect to minor species, new products exclusively for this category of animals are not being developed in Canada because of market size. As indicated previously, a lack of clarity around the MUMS program also makes it difficult to define a timeline for development of products that may have minor species indications – best estimates by industry participants in the 2020 survey indicated that development time for this class of products has increased by anywhere from 1-7 years since 2015.

However, Health Canada's initiative with respect to joint product reviews with other jurisdictions (*e.g.* Australia and New Zealand) represents a very positive step towards facilitating minor species products reaching the small Canadian market.

Figure 5: Change in Average TIME to develop a Major New Pharmaceutical product



Impact of Regulations on TIME to develop a major new BIOLOGICAL product

Have REGULATORY FACTORS caused a change in the AVERAGE LENGTH OF TIME it takes you to develop a major new biological product in Canada (from initial research to final market authorisation), compared to 2015?

Most major veterinary biological products available on the Canadian market are developed, manufactured and initially licensed in other jurisdictions (US, Europe, New Zealand and Australia). Since 2015, only 2 major new veterinary vaccines have been developed and licensed in Canada. Both were developed for use in fish, but only one was developed and licensed for domestic distribution, whereas the second was developed for export only.

Development times vary widely between biological products developed for export vs. those developed for domestic distribution, because the former depend heavily on a coordination of regulatory reviews in the country of export with the Canadian regulatory review.

There have been no regulatory factors in Canada that have caused a significant change in the average length of time required for development of products for domestic distribution since 2015.

COST of developing a major new PHARMACEUTICAL product

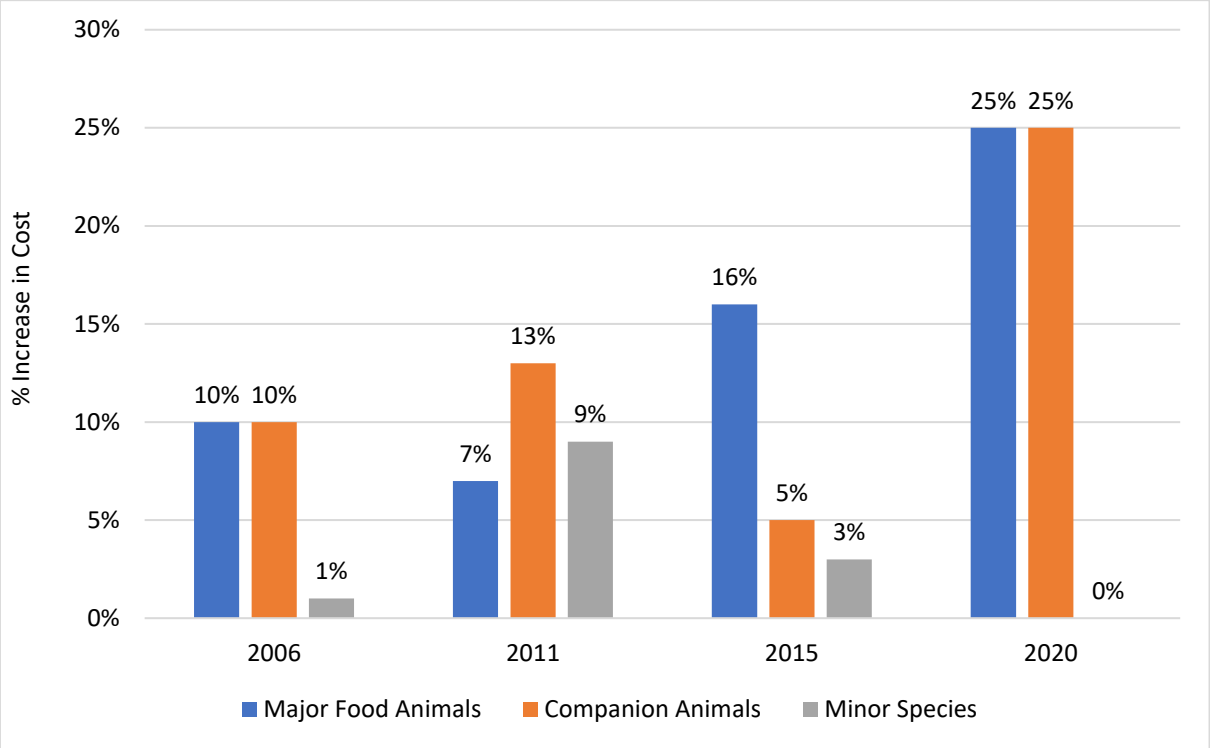
Thinking about the AVERAGE COST of developing a major new PHARMACEUTICAL product in Canada (from initial research to approval) for all possible species and indications for that product, compared to 2015 have REGULATORY FACTORS caused this cost to change in real terms? Make separate estimates for major livestock species, companion animals, and minor species.

Since 2015, the cost of developing a major new pharmaceutical product in Canada has **increased by 10-25%** for both major food animals and companion animals, with increases being closer to 25% for entirely novel drugs.

In addition, there is industry concern that proposed Environmental Risk Assessment regulatory amendments could drive these increases up as high as 26-50%.

New products are not being developed specifically for minor species or minor uses, as companies are unwilling to develop new data not already required by EU or USA, the costs of which are not justified when there is inadequate return on investment due to Canadian market size.

Figure 6: Change in Average COST to develop a Major New Pharmaceutical product



COST of developing a major new BIOLOGICAL product

Thinking about the AVERAGE COST of developing a major new BIOLOGICAL product in Canada (from initial research to final market authorisation) for all possible species and indications for that product, compared to 2015, have REGULATORY FACTORS caused this cost to change in real terms? Make separate estimates for major livestock species, companion animals, and minor species.

Only one of the companies participating in the current survey developed a major new biological product for domestic distribution in Canada since 2015, and it was the only product to be licensed over this five-year period. As a result, information about the average cost of developing a major new biological product has not been provided.

Impact of specific areas of regulation on innovation ability

Thinking about Government Regulations in Canada, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO INNOVATE successfully?

The most helpful regulatory areas with respect to impact on the industry's ability to innovate in Canada were those relative to marketing authorisation regulations for pharmaceuticals, biologics, and feed additives, as well as protection of intellectual property with respect to patents. This serves to illustrate the importance of a regulated market to the ability of companies to innovate.

In 2017, Canada introduced regulations related to antimicrobials, which included federal reporting requirements for medically important antimicrobials, closed an "Own Use Importation" loophole that had existed previously, and implemented better control over the importation of antimicrobials. While these changes did result in higher product costs for companies in Canada, they were also beneficial to the sector by ensuring better oversight over the manufacturing, importation, compounding and use of antimicrobials, thus providing a mechanism to improve the quality of all antimicrobial products on the Canadian market, including compounded ones. As a result, Disease Resistance Regulations were categorized in Table 4 below as having no impact overall on companies' ability to innovate.

Regulations around marketing authorisations for pesticides, and manufacturing and quality inspection requirements were reported as unhelpful.

Maximum residue limit (MRL) methodologies (tissues used) and calculations (food basket input) used by Health Canada's Veterinary Drugs Directorate (VDD) are not aligned with those used by other developed countries. This renders the MRL regulatory area unhelpful as companies are unsure of how MRLs are being calculated due to inconsistencies in the availability of this information from VDD.

Regulations around GMP requirements for APIs are also categorized as inefficient and unhelpful, as regulatory changes introduced in 2017 extended GMP requirements to low-risk APIs that have had no history of quality or safety issues, despite their long-term use. Health Canada's Regulatory Operations and Enforcement Branch also needs to modernize its processes to allow for efficiencies that can fast track reviews to ensure timely product availability. The current 250-day review performance standard for Drug Establishment Licences (DELs) places Canada at a significant disadvantage with respect to other jurisdictions.

Table 4: Impact of regulation on ability to innovate

Areas of regulation	*Very Helpful*	*Helpful*	*No Impact*	*Unhelpful*	*Very Unhelpful*
Marketing Authorisations (VDD)		X			
Marketing Authorisations (CFIA-CCVB)		X			
Marketing Authorisations (CFIA-AFD)		X			
Marketing Authorisations (PMRA)				X	
Maximum Residue Limits				X	
Good Laboratory Practice			X		
Biotechnology Regulations			X		
Disease Resistance Regulations			X		
GMP for API Requirements				X	
Environmental Regulations (Ecotox)				X	
Manufacturing/Quality Inspection Requirements				X	
Protection of Intellectual Property–commercial data				X	
Protection of Intellectual Property–patents		X			
Electronic format for access to guidance/policy documents					X

In the area of environmental regulations, while companies recognize that it is helpful to have a regulatory framework in place for this, there are significant problems with Canada's current system. Current environmental regulations are not geared towards veterinary drugs and are furthermore not aligned with those of the US or the EU. At the time of the writing of this report, new regulations are

under development, but concerns about the likelihood of future alignment with other jurisdictions remain, and there is a risk that the new regulations may create new requirements for generation of data which would be needed only for Canada, but not for larger markets like the US and the EU.

The last regulatory area identified as being in the unhelpful category is that of protection of intellectual property with respect to commercial data, where extensions to protection of data need to be provided in order to support the addition of new species.

Finally, the regulatory area which was identified as being least helpful (i.e. in the "Very Unhelpful category) was that relative to Electronic formats for access to guidance/policy documents. Canadian government websites require significant upgrades in order to become more user friendly, convert old forms into new formats, allow browsers other than Internet Explorer, and newer versions of Windows.

Incentives from the Patent Law and Innovative Drug Registry due to data protection/market exclusivity

Considering the length of data protection (market exclusivity) given by the Patent Law and Innovative Drug Registry in Canada, to what extent do you consider it to be an incentive?

Within the Canadian context, protection of intellectual property occurs through two mechanisms:

1) 8 years of data protection for new veterinary substances
2) Up to 20 years of patent protection. An additional 2 years of protection is possible if a Certificate of Supplementary Protection (CSP) is granted.

In reality, however, veterinary drugs rarely benefit from this full protection as a good portion of the patent validity has already elapsed by the time the veterinary medicinal product is marketed.

Intellectual property protection incentives for subsequent species or indications for pharmaceuticals, as well as for biologics, are not applicable to the Canadian situation. They also do not apply to minor species, as in the Canadian context, these products are considered not-new and are off-patent.

Table 5: Incentives due to data protection/market exclusivity

	Years	*Very Helpful*	*Helpful*	*No Impact*	*Un-helpful*	*Very Un-helpful*
VDD – first approval	Up to 20	X				
VDD subsequent species or indications	N/A				X	
VDD – minor species	N/A				X	
CFIA – first approval biologics	0					X
CFIA subsequent indications biologics	N/A					X
CFIA – first approval feed medicating ingredient	0					X
CFIA subsequent indications feed medicating ingredients	0					X
CFIA - minor Species	0					X
PMRA – first approval	12					X

Section C - COMMERCIALISATION OF EXISTING PRODUCT

Impact of regulation on ability to exploit existing products

Below is a list of potential FACTORS RELEVANT TO THE EXPLOITATION OF EXISTING PRODUCTS in the animal health industry in Canada. Which of these, if any, are significant for the exploitation of your existing products? (Please rank from 1 for 'most important' to 12 for 'least important'. In the workshop, please agree a final ranking by consensus.)

The top three most important regulatory factors relevant to the exploitation of existing products by the animal health industry in Canada are reported as being GMP requirements for APIs, the regulatory framework for maintenance/extensions of licences, and pressure from competitors, including parallel imports and generics.

The three least important factors are legal restrictions on advertising, labels, trademarks and communication; demand volatility in certain segments; and inadequate intellectual property protection (commercial data and patents).

Table 6: Impact of regulation on ability to exploit existing products

Factor	*Importance*
GMP for API Requirements	1
Canada's regulatory framework for maintenance/extension of licences	2
Pressure from competitors (including parallel imports and generics)	3
Small size of market segments	4
Lack of availability of financial resources	5
Negative consumer attitudes	6
Lack of skilled staff	7
Closure of the Canadian market and/or other geographic markets for certain products	8
Legal restrictions on advertising, labels, trademarks and communication	9
Demand volatility in certain segments	10
Inadequate intellectual property protection (commercial data & patents)	11

Effects of government regulations on business

Do government regulations in Canada have any of the following effects on your business? (Please rank from 1 for 'most important' to 11 for 'least important')

The most important effect that government regulations in Canada have on business in the Canadian animal health industry is that they are leading to the removal of profitable products from the Canadian market as a result of two main regulatory initiatives that have increased product maintenance costs:

1) The introduction of GMP requirements for APIs; and
2) New Health Canada service fee increases, which begin to come into force in April 2020 are further anticipated to drive the costs of maintaining products on the market up to unsustainable levels

The removal of growth promotion claims from labels of medically important antibiotics since 2015 also resulted in the disappearance of some products from the market. In some cases, the extra data required to add new (non-growth promotion) claims to old products reflecting actual product use for treatment, which had been facilitated for years by extra-label drug use, made it difficult to keep these older products on the market. However, this regulatory change was supported by industry as an important contribution to ensuring responsible antimicrobial use and stewardship in veterinary medicine and aligned with similar changes implemented in the US and the European Union.

Table 7: Effects of government regulations on business

Effect	*Importance*
Remove profitable products from the market	1
Create disproportionate costs for maintaining/extending marketing authorisations	2
Divert management time	3
Divert financial resources away from the development of new, innovative products	4
Restrict the extension of existing technologies to additional species/indications	5
Increase the cost of production	6
Create significant uncertainty	7
Fail to protect intellectual property (patents & commercial data) adequately	8
Limit the use of innovative marketing methods	9
Increase the cost of distribution and marketing	10
Other: Lack of alignment with the USA on the VHP program, generic drug requirements, and potentially environmental risk assessments, etc)	

Impact of regulation of autogenous vaccines in Canada on vaccine innovation

How does the regulation of autogenous vaccinates in Canada affect your ability to bring new innovative vaccines to market?

The regulation of autogenous vaccines has no effect on the ability of Canadian companies to bring new innovative vaccines to market.

Section D - REGULATORY PREDICTABILITY & QUALITY

Predictability and quality of Canadian regulatory procedures

(a) Do the Canadian regulatory agencies as currently managed provide you with the regulatory predictability that you need and the regulatory quality you expect? (b) If not, please tell us what the top issues are with each agency and what might be done about them (your proposed solutions moving forward).

Tables 8 and 9 below show the outcomes of the questions on predictability and quality of Canadian regulatory procedures. Predictability and quality of regulatory procedures for veterinary drugs and biologics was assessed positively overall by Canadian companies participating in the survey, with the PMRA scoring somewhat lower as a result of its limited expertise in the veterinary space.

One area of particular concern is the identified lack of predictability in Feed Additives, which in 2019 had a minimum of one year's backlog in submissions with no indications of a plan to address the situation. At the time of writing of this report, CFIA's Feed Division has taken positive steps towards resolving this issue, with the development of a strategy to clear the backlog of submissions and ensure that future submissions can be reviewed more efficiently.

A comprehensive response to the overall situation and suggested areas for improvement are laid out below in Table 9.

Table 8: Predictability and quality of Canadian regulatory procedures

		VDD (for drugs)	CFIA-CCVB (for biologicals)	CFIA-AFD (Feed Additives)	Pest Management Regulatory Agency
Regulatory predictability	Always				
	Mostly	X	X		
	Sometimes				X
	Never			X	
Regulatory quality	Always				
	Mostly	X	X		X
	Sometimes			X	
	Never				

Table 9: Proposed solutions to improve regulatory predictability and quality

Health Canada - VDD & ROEB	**VDD**: • Screening for information not in guidance; updating and communicating of guidance requirements on a regular basis • Availability of up-to-date guidance • Clarity in the MUMS program • Consideration of import tolerance and conditional licensing programs • A renewed commitment for alignment with the USA (e.g. generic drug assessments, VHPs, RCC technical review processes and timelines, environmental risk assessments • Chemistry and Manufacturing Division - VDD needs to be more consistent in submission evaluations to improve predictability **ROEB:** • Need for development of a more user-friendly approach by triaging work, avoiding redundancy in the review process, providing adequate guidance, and increased efficiency in administrative processing of duplicate submissions for sites and activities
CFIA- AFD and CCVB	**AFD:** • Need for leadership in managing and assessing risk • Addressing the backlog of submissions that has been identified by numerous stakeholders (e.g. livestock and poultry associations, retailers) as a significant hurdle. **CCVB:** • Current concentration of knowledge and corporate memory in a small number of CCVB staff requires a need for succession planning • Guidelines are often vague, resulting in great variation and subjectivity in interpretation by reviewers. • Clarity and consistency of the review process needs to be improved. • Better alignment of the review process to support registration of EU approved vaccines.
PMRA	The PMRA knowledge base is focused primarily on crop applications. An improved understanding of products for veterinary uses needs to be developed. Collaboration with the VDD, industry and other developed regulatory authorities regarding veterinary products needs to be initiated to improve the veterinary pesticide review process. Some progress has already been made by adopting this approach.

Section E - REGULATORY TRENDS

Recent beneficial changes to Canadian regulatory frameworks

What beneficial changes have occurred in the regulatory framework SINCE 2015?

Table 10 below outlines recent improvements to the Canadian regulatory framework by regulatory body.

One noticeable development has been the willingness to engage in shared or joint reviews, such as the Canada-US Regulatory Cooperation Council process, and the tripartite Canada-Australia-New Zealand shared reviews, which evolved through Canada's participation in the VICH initiative.

The improved pharmacovigilance reporting systems have been appreciated.

Table 10: Recent Improvements to the Canadian regulatory frameworks

Regulatory Body	Improvement
VDD:	• Ongoing progress towards better harmonization through shared and joint reviews, such as the Canada-US Regulatory Cooperation Council process, and the tripartite Canada-Australia-New Zealand • Amendments to the Food and Drug Act regulations which allowed the launch of the Veterinary Health Product (VHP) program regulating low-risk, unconventional products, and its extension to include products for food-producing animals as well as companion animals (see Section G below for more details) • Use of pre-submission meetings to clarify expectations and make the registration process smoother • Clearer review times • Electronic submissions • New pharmacovigilance reporting modalities, which allow reporting to be done electronically through PVWorks
CFIA:	• Direct fed microbials • Pharmacovigilance reporting for biologics.

Expected changes that have NOT occurred in Canadian regulatory frameworks

What beneficial changes have NOT occurred in regulatory frameworks SINCE 2015 in spite of expectations of change?

Table 11 below outlines changes that have not occurred in the Canadian regulatory framework, despite industry expectations of changes or improvements, organized by regulatory body.

There are some common themes with other sections of the report, such as the impact of increased fees and the delays in updating guidance documents, and the disproportionate impact on the MUMS product category.

Table 11: Expected changes that have NOT occurred in Canadian regulatory frameworks

Regulatory Body	Change Expected but not Seen
Health Canada/VDD:	• Clarity for a MUMS program • Concerns raised by industry about new veterinary drug service fees proposed for 2020-2027, which will not be supported by market size, were not adequately addressed • Further modernization in program delivery (e.g. use of foreign reviews and decisions, pharmacovigilance) • Fee reductions need to support MUMS submissions • Updated guidance (*e.g*. the fee form is not current; this results in different reviewers allowing different things) • Clear policy on Classification Requests • Secure, modern gateway for E-submissions
ROEB:	• Greater flexibility in the approach to risk management, which recognizes the reduced risks of using animal versus human products. • Oversight and inspection of compounding facilities, and creation of a level playing field with respect to enforcement of GMP requirements • More efficient review process for Drug Establishment Licences • Modernization in program delivery (e.g. use of foreign decisions and reviews) • Mutual recognition agreement with the US

Recent changes to Canadian regulatory frameworks causing the most problems

What regulatory changes SINCE 2015 have given you the most problems and why?

Table 12 below outlines the most problematic (from an industry perspective) changes which have been made to the Canadian regulatory framework since 2015.

As reported in other sections of this report, the key issues centre around the manufacturing quality aspects of the data requirements.

Table 12: Recent changes to the Canadian regulatory frameworks that are problematic

Regulatory Body	Issue
Health Canada/VDD:	• Increased product costs as a consequence of new GMP requirements for APIs, and antimicrobial reporting requirements, especially when considered in the context of the small Canadian market size • Meeting additional requirements such as impurity profiles for generic drugs • Requirements for a unique Canadian Drug Master File
ROEB:	• GMP API requirements and associated challenges with sourcing of active ingredients • A lack of efficiencies (e.g. triaging and improved electronic databases) in program delivery processes to improve timeframes and remove redundant work

Business decisions influenced by regulations

Have regulations played a major role in influencing you to take any of the following major decisions over the last five years?

For this 2020 report, Canadian regulatory frameworks were found to have had a significant influence on Canadian companies' major business decisions with respect to investing in production outside of Canada, increasing product ranges in Canada, restricting (geographic) market focus in Canada, reducing coverage of species or indications in Canada, and focusing on new technologies in Canada.

In addition, Canadian regulations also had a lesser degree of influence on business decisions related to locating R&D facilities both within and outside Canada, switching R&D budgets to labs outside Canada, reducing product ranges in Canada, increasing coverage of species or indications in Canada, focusing on existing/older technologies in Canada, developing certain product technologies in Canada and avoiding certain product technologies in Canada.

The full range of business decisions that Canadian participants in the 2020 survey were asked about is presented in Table 13.

Table 13: Influence of the Canadian regulatory frameworks in major business decisions

Major Decisions	***Not Done***	***Done but regulations no influence***	***Done & regulations some influence***	***Done & regulations a significant influence***
Locate R&D Facilities inside Canada			X	
Locate R&D Facilities outside Canada			X	
Switch R&D budgets to labs inside Canada		X		
Switch R&D budgets to labs outside Canada			X	
Invest in production inside Canada		X		
Invest in production outside Canada				X
Increase product range in Canada				X
Reduce product range in Canada			X	
Increase (geographic) market focus in Canada		X		
Restrict (geographic) market focus in Canada				X
Increase coverage of species or indications in Canada			X	
Reduce coverage of species or indications in Canada				X
Buy businesses in Canada		X		
Sell or close businesses in Canada		X		
Focus on new technologies in Canada				X
Focus on existing/older technologies in Canada			X	
Introduce more 'breakthrough' products in Canada		X		
Introduce fewer 'breakthrough' products in Canada		X		
Develop certain product technologies in Canada			X	
Avoid certain product technologies in Canada			X	

Section F - HOPES AND EXPECTATIONS FOR THE NEXT 5 YEARS

Changes in regulatory approach and their impact on the future

The following trends or changes in regulatory approach have been taking place recently and may well have an impact in future. What impacts do you expect these changes to have on your business in the next 5 years?

The trends and changes identified in Table 14 below were assessed as being split fairly evenly between those expected to have positive impacts on business in Canada over the next 5 years, and those expected to have negative impacts.

Trends or changes perceived as likely to be **very helpful** to Canadian animal health industry companies included an increasing trend to move from a zero-risk approach to a benefit-risk assessment approach and acceptance of JECFA agreements for residues of non-contentious molecules.

Trends perceived as likely to be **helpful** included moves towards electronic submissions and moves towards a common technical document, especially where this reflects alignment with VICH Guidelines.

In contrast, the trends and changes perceived to be **unhelpful** to Canadian business in the animal health space included: increasing transparency with respect to data disclosure; a trend towards wider participation in the regulatory process (including more public comment); and increasing requirements for post-marketing surveillance and pharmacovigilance, which are often applied inconsistently across products. Increasing globalisation of post-marketing surveillance outcomes, while beneficial in terms of generating efficiencies in the system internationally for multinational companies, simultaneously creates challenges at the national level. The tracking and reporting to Health Canada of adverse events occurring in other jurisdictions requires Canadian affiliates to dedicate additional time and resources to these tasks.

Table 14: Impact of trends and changes in regulatory approach in the next 5 years

Trend or Change	*Very helpful*	*Helpful*	*No impact*	*Un-helpful*	*Very un-helpful*
Increasing transparency with respect to data disclosure				X	
Trend to wider participation in regulatory process, including public comment				X	
Increasing trend to move from a zero-risk approach to a benefit-risk assessment	X				
Increasing requirements for post-marketing surveillance & pharmacovigilance				X	
Increasing globalisation of post-marketing surveillance outcomes				X	
Acceptance of JECFA agreements for residues of non-contentious molecules	X				
Moves towards electronic submission		X			
Moves towards a common technical document		X			

Foreign regulatory decisions' impact on innovation ability

Does the use of foreign regulatory decisions in the Canadian review process impact your ability to innovate?

The use of foreign regulatory decisions in the Canadian review process has a positive impact on Canadian companies' ability to innovate. It has the potential to significantly reduce regulatory costs in the future and introduce greater efficiencies in regulatory oversight processes. Industry would like to see the use of foreign regulatory decisions by Canadian regulators greatly expanded.

Changes still wanted in Canadian regulatory approach

What changes do you still want to see and why?

Table 15 below outlines the changes still wanted by industry in the Canadian regulatory approach, organized by regulatory body.

For the VDD an underlying theme is the desire to seek greater regulatory efficiencies arising from better international alignment.

For the ROEB it appears the desire is to see a greater understanding of the characteristics of the veterinary medicinal products market.

Table 15: Changes still wanted in Canadian regulatory approach

Regulatory Body	Change Wanted
VDD:	• Move to greater use of benefit-risk assessment approaches • Updating of guidance documents (GLs) to support single review passes for products • Increased use and acceptance of foreign reviews and decisions • Move to dose ranges and alignment in maximum residue assessments • Elimination of redundant need for endotoxin testing in favour of alignment with the EU requirement • Alignment over the interpretation of VICH guidelines.
ROEB:	• Robust triaging of foreign site assessments • Improved timeliness of reviews using modern system approach • Working with manufacturer on observations before going public • Better understanding of veterinary requirements by inspectors • Better oversight and more inspection of compounding facilities to ensure a level playing field, as well as the safety and efficacy of compounded products.

Section G - REGULATORY COOPERATION AND SPECIAL PRODUCT CATEGORIES

Regulatory trend for regional regulatory cooperation

(a) Does your regulatory authority engage in any forms of regulatory cooperation, such as joint reviews or parallel assessment, with another regulatory authority? (b) If yes, how do joint reviews or parallel assessment between Canada and another country impact your ability to innovate?

The Canadian Veterinary Drugs Directorate (VDD) engages in joint and parallel reviews. In general, this process has had a positive impact on innovation. The new processes have helped to ensure market availability of product in Canada at the same time as other developed jurisdictions, as the grouping of markets can help to create a critical mass for small products or bring products to the small Canadian market.

However, a better balance in terms of what is expected of companies to accommodate joint reviews would be beneficial, as current expectations do not necessarily support all company sizes equally.

Special categories of products exempt from some data requirements for registration

In your country do "special categories" of product exist, such as "minor species", or "generic" for which there is an exemption from certain data requirements (e.g. registration can be obtained with an abbreviated or abridged data dossier)?

Special categories do exist; however, Abbreviated New Drug Submissions requirements and minor use/minor species (MUMS) requirements need to be consistent with other jurisdictions. A MUMS definition needs to be developed (including minor uses in major species) and should incorporate economic parameters into assessment criteria. Consideration needs to be given by VDD to allowing a conditional approval, as is the case in other jurisdictions.

In addition, since amendments to the Food and Drug Act regulations in 2017 created a new regulatory pathway for low-risk products through the Veterinary Health Products (VHPs) program, a new category of products has emerged. VHPs are defined as low-risk products in dosage form, which are used to maintain or promote health and wellness in animals, and make no claims with respect to preventing, treating or curing a disease. The VHP Program officially replaced the previous Low-Risk VHP Interim Notification Pilot Program on November 13, 2017, and also expanded the scope of the interim pilot program beyond companion animal products to also include products for food-producing animals.

In order to be legally marketed and sold in Canada, Veterinary Health Products (VHPs) must obtain a Notification Number (NN) from the VDD via the VHP Notification Program. VDD administers the notification program through a customized end-to-end web application. VHPs can only be formulated from a list of Health Canada approved ingredients. Ingredients permitted for use in VHPs are set out in List C, which is incorporated by reference in the Food and Drug Regulations, and is included within the web application, as the List of Permitted Substances (LPS). The list currently includes 775 actives, 953 excipients, and 137 traditional Chinese medicines. A thorough risk assessment is conducted before an ingredient is added to the LPS, and ingredients permitted for use in food animals are subject to a more rigorous assessment for food safety and human safety.

The VHP program is still fairly new, and there have been some initial challenges in its implementation. The VHP Notification process has a 30-day performance standard target, which for the period covered by this survey was not being met consistently, and there has been a lack of enforcement with respect to non-compliant notifiable products in both companion and food-producing animals. There has also been some inconsistency in application of the program, as in some cases, new products have been denied claims that other similar products were already granted.

Proposed solutions to improve the regulatory predictability and quality of the VHP Notification Program include development of clear guidance and a screening checklist and ensuring that all products have approvable claims.

5. Conclusions and recommendations

Regulatory environments evolve slowly, and the Canadian environment is no exception. As a result, many of the issues, hopes and expectations identified in previous surveys are carried forward in this one. Yet Canadian companies' overall perception of the regulatory environment within which they operate is a positive one and appears to represent an improvement over perceptions reported in previous surveys.

At the same time, many challenges continue, not least of which are ongoing increases in the costs of not only product development, but also product maintenance. Novel approaches to risk assessments, increased harmonization across jurisdictions paving the way to more acceptance of foreign decisions, and identifying efficiencies in the regulatory system (*e.g.* eliminating redundancies, streamlining processes across departments involved in review and approvals) all represent opportunities for regulators to work with industry on reducing unnecessary costs, while maintaining appropriate oversight for veterinary products.

As a result, the need for further modernization of the Canadian regulatory framework is another common thread that emerges repeatedly throughout this report. Ideally, such a modernization would result in a predictable system that manages risk and supports continued regulatory harmonization/convergence, while remaining sufficiently nimble to address changing needs within veterinary medicine and to support innovation.

Key recommendations:

- Continue the drive for greater harmonisation and alignment with other developed countries
- Build on efforts to make regulatory processes and procedures timelier and more efficient
- Address the issue of high expenditures on mandatory defensive R&D, and proposed increases to service fees for veterinary drugs for 2020-2027
- Ensure that risk assessments related to environmental safety and antimicrobial resistance are appropriate and proportionate to the veterinary sector
- Continue to build more opportunities for dialogue between industry, regulators and other key stakeholders which will support working together for the most successful outcomes
- Continued commitment to regulatory cooperation and alignment between trusted regulators and international harmonisation and convergence

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Glossary of Abbreviations

AFD	Animal Feed Division
AH	Animal Health
API	Active pharmaceutical ingredient
CAHI	The Canadian Animal Health Institute
CCVB	Canadian Centre for Veterinary Biologics
CFIA	Canadian Food Inspection Agency
DEL	Drug Establishment License
FDA	US Food & Drug Administration
GBS	Global Benchmarking Survey
GMP	Good Manufacturing Practice
ICSA	Institut Canadien de la Santé Animale
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MDR&D	Mandatory Defensive R&D
MRL	Maximum Residue Limit (or level)
MUMS	Minor Species, Minor Uses-Minor Species
NOC	Notice of Compliance
PMRA	Health Canada's Pest Management Regulatory Agency
R&D	Research and Development
ROEB	Regulatory Operations and Enforcement Branch (part of Health Canada); carries out inspection and enforcement activities on behalf of Health Canada
VDD	Canada's Veterinary Drugs Directorate
VHP	Veterinary Health Product
VICH	Veterinary International Cooperation on Harmonization (of Technical Requirements for Registration of Veterinary Medicinal Products)

Report prepared by Dr. Catherine Filejski, President & CEO of the Canadian Animal Health Institute (www.cahi-icsa.ca) as part of a HealthforAnimals initiative to support informed policy making in the animal health sector globally.

This report and reports on the other markets included in the benchmarking survey are available at: HealthforAnimals.org/GBS2020

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