

# Canada's Health Department Proposes Non-competitive Regulatory and Maintenance Service Fees for Veterinary Drugs

On October 21, 2017, Health Canada publicly released its Fee Proposal for Drugs and Medical Devices. The *Service Fee Act* was introduced as part of an Omnibus Budget 2017 Bill and in the Institute's opinion did not get the scrutiny it needed, particularly as it relates to public/private good and competitiveness. The following outlines the Canadian Animal Health Institute (CAHI) concerns about the unintended consequences of the proposed fees should they be introduced as is in 2019.

Analysis of the proposed service fees for veterinary drug review and maintenance brings the CAHI to the conclusion that should this proposal come to be implemented, as is, sales for 58% of the current livestock products will not support a new registration, while 52% of companion animal product sales will not support introduction to the Canadian market. If innovation costs of 5% of the total R&D costs are included in the calculation, 79% of the livestock products (74% for companion animal) fall below the financial threshold to support product registration and launch in Canada (Appendix 1).

Consequently, Canada will lose products currently licensed for the Canadian market and many new products will never seek marketing authorisation in this country. The new fees will effectively undermine all current initiatives put in place to ensure responsible or prudent use of veterinary drugs, particularly medically important antimicrobials (MIA), as veterinarians and producers will look to manage animal health and welfare in the absence of licensed product. It will also undermine research and development into alternatives to antimicrobials, a pillar of the Canadian federal government's *'Antimicrobial Use and Resistance Framework'* document, as well as its *Plant and Animal Health Strategy* targeting animal disease management.

Increased compounding of veterinary drugs, illegal importation, and use of unapproved animal medications will require restructuring of Canada's veterinary drug programmes. This is due to fewer resources being needed to manage the reduced submissions submitted, while greater compliance and enforcement measures will need to be taken to manage the increased risk of non-compliant veterinary drug use. Furthermore, veterinarians and food animal producers will not have access to the same health management tools as those in other countries that we compete with, resulting in global competitiveness, market access and trade implications.

CAHI is not opposed to paying service fees but does believe that the fees should be competitive relative to the services provided, the market size and public good provided by veterinary drugs. The following outlines our thoughts in these areas and the Fee Proposal itself.

## Regulatory Performance Standard Competitiveness

Further to the Fee Proposal being discussed, it needs to be known that the Veterinary Drugs Directorate (VDD) did not update its fees in 2011 along with the human drugs and

medical devices. This was largely because it was in a state of rebuilding its services to meet international regulatory performance standards. Serious management issues consumed the VDD for over a decade to the detriment of the veterinary drug review process and the competitiveness of Canadian animal health manufacturers. A regulatory benchmarking survey done by the International Federation for Animal Health (now operating as HealthforAnimals) in 1999 found that VDD regulatory performance lagged behind other developed countries including the EU, USA, Australia, New Zealand and Japan. Ultimately the most serious consequence of this situation was that Canadian animal owners did not have timely access to the health management tools their counterparts had in other countries.

Without access to new medicines, veterinarians were also unable to deliver modern veterinary services to their patients. In fact, in the late 1990s it was recognised that licensure of Canadian veterinary drugs lagged by about seven (7) years behind that of the USA. Significant improvements needed to be made and it is only in the last few years that VDD has been able to provide competitive regulatory services for Canadians.

## Market Size

The Canadian animal health business is only 2.5% of the global animal health market. The human pharmaceutical industry in Canada, which benefits from socialised medicine, is a 35 times larger market than the Canadian animal health market. From a transnational corporation perspective, animal health in Canada is considered a lower-tier commercial market. Therefore, Canada, at 10% of the sales of the USA, has a lower return on investment and is a lower priority for registration. Drug innovation costs are \$29 million and \$39 million Canadian for companion and livestock drugs, respectively, and the return on investment is not realized for three to seven years. For Health Canada to calculate the service fees based on program, corporate and capital costs without consideration of the market size and benefit to society makes no sense. It becomes a budgeting exercise that will stymie innovation and negatively impact the availability of safe and effective animal health products in the Canadian market. A consequence of this situation will be the introduction of greater risks to Canadians due to use of unlicensed animal drugs. As noted previously, increased pressures on Health Canada compliance and enforcement costs will be a consequence.

With Canada being only a small player in the overall global animal health market, it is estimated that any approved "blockbuster" drugs presently sold in the Canadian veterinary market would represent only 2-4% of the industry's current approved drug portfolio, with over 50% of this portfolio falling into sales of less than \$500,000 annually. The proposed fees will make justifying a Canadian registration next to impossible when registration and maintenance fees surpass yearly sales. Niche products are likely to disappear from the market and alternative products not come to the market due to the inability to justify high regulatory costs with the small Canadian market size.

### Public Good of the Veterinary Drug Programme

Registration of animal drugs is a benefit to both animal health companies and to our public. Our pets are important household members providing emotional stability and health benefits to their owners. Animal health products contribute to the welfare of our food and companion animals, and to food safety in the case of production animal drugs. Keeping our animals healthy is also critical to keeping people healthy. According to the American Centers for Disease Control and Prevention *"Scientists estimate that more than 6 out of every 10 known infectious diseases in people are spread from animals, and 3 out of every 4 new or emerging infectious diseases in people are spread from animals. Every year, tens of thousands of Americans will get sick from harmful germs spread between animals and people."*<sup>71</sup> How can we not recognise our public and animal patients as beneficiaries of animal medications?

The government of Canada is implementing new measures to ensure the responsible or prudent use of medically important antimicrobials used in veterinary medicine. This action is a part of the stewardship pillar of the Federal Government's 'Framework on Antimicrobial Use and Resistance'. Lack of accessibility to licensed veterinary drugs will undermine this initiative as animal owners and veterinarians seek options to manage animal welfare using compounded and other unlicensed products. Furthermore, the Federal Plant and Animal Health Strategy will be challenged to meet its goals to manage animal diseases without access to the same health management tools as those used in other developed countries that food animal producers compete with.

The take home points from the above comments are:

- Veterinary drug regulatory services need to meet equivalent regulatory performance standards to that of other developed countries;
- Veterinary drug service fees in Canada need to reflect market size if they are indeed to be a benefit to the manufacturer and not a barrier to availability of animal drugs; and
- The veterinary drug service fees need to account for the benefit Canadian food and companion animal owners and our public receive in having access to health management tools that ensure animal welfare and in the case of production animals, food safety.

To meet these three points, CAHI agrees that veterinary drug service fees must be revisited and modernised; however, consideration must also be given to ensure Canadian veterinarians and animal owners have access to the same health management tools as their counterparts in other countries. This is particularly true for food animal producers who are competing in global markets. As an example, Appendix 2 identifies issues relating to Post-NOC changes in accessibility and pricing of animal drugs in Canada relative to other markets. Additionally, the current fees do not take into account the reduced burden when a review is shared with another competent foreign agency which should lower costs. Canadian veterinarians need access to new medications so they can deliver modern veterinary services to their patients.

Without modernisation of the veterinary drug fee structure and without it reflecting Canada's market size, the following will be impacted:

- Little incentive for companies to participate in collaborative evaluations or joint reviews;

- No incentive for companies to submit products for minor use and minor species (MUMS), compatibility, or niche markets;
- Veterinarians will increasingly be required to prescribe drugs extra-label since manufacturers will not look to expand label claims due to high regulatory costs;
- Increased compounding of veterinary drugs to meet animal health and welfare needs in the absence of licensed products, which will increase risk, veterinarian liability and further erode the competitiveness of licence-holders with that of compounding manufacturers (Appendix 3);
- Enforcement and compliance resources will subsequently need to be increased as an illicit market grows to meet animal owner needs; and
- Increased emergency drug release (EDR) requests resulting in the generic registration path not being available, thus having negative unintended consequences on veterinary drug pricing and availability, as well as increasing product costs to the animal owner by having to use the EDR process.

### Rethinking Veterinary Drug Service Fees in Canada in Support of Animal Welfare and Food Safety! CAHI

The CAHI requested Health Canada to rethink the fees associated with delivery of its veterinary drug programme. CAHI has submitted a number of recommendations specific to the Fee Proposal, as well as providing a comparison of the fees proposed in Canada with that of Australia (Appendices 4 and 5), which has a similar market size and tax base.

Appendices 4 and 5 are analyses conducted by CAHI of the veterinary drugs review and DEL process for selected submission types. Generally, Health Canada is proposing to charge significantly more fees than Australia, which is of a similar market size to Canada.

As mentioned, CAHI is aware that Australia charges a levy on annual sales for approved products; however, considering the difference in regulatory fees between Australia and what is proposed for veterinary products in Canada, the levy would account for 10 – 15 years of sales to equate to the Canadian filing fee.

Canada is asking for a significant up-front regulatory investment on top of the product development investment companies already make before having a return on investment. This situation will negatively impact both products coming into, and staying in, the Canadian market. We anticipate fewer new products, supplementary new drug submissions, MUMS and RCC submissions based on the proposed fee structure. The high veterinary drug service fees being paid in advance of a return on investment and without accounting for its market size do not make good business sense and will result in reduced investment in veterinary drug products. Similarly, they do not make good business sense for Health Canada and Canadians when resources will need to be directed to a consequential higher-risk and illicit market due to illegal importation and compounding of veterinary drugs to meet animal welfare needs.

### Conclusions

#### What does CAHI propose?

- Recognition of the veterinary drug regulatory work of other competent agencies. A strong case can be made for accepting the reviews of competent foreign agencies such as the USA Food and Drug Administration

(FDA), which we have gained confidence in through the Regulatory Cooperation Council (RCC) work. Canada should exploit the good work of the FDA Center for Veterinary Medicine and accept the reviews it does relative to human safety, companion animal clinical efficacy, manufacturing and, where appropriate, clinical efficacy for production animals. We must be sure that our regulatory services add value. Repeating a review done by another competent agency does not add significant value to Canadians. Elimination of duplicate services to that of other competent agencies would help to facilitate a downward adjustment to fees that would be more in line with the Canadian market.

- The current DEL fees presented are not transparent when reported as an average. We believe the fees are too high for veterinary drugs and lack balance based on risk of activity performed (*e.g. a fee for a non-sterile fabricator is slightly less than for an importer; significantly reduced fee for packager/labeller activity*). We question the rationale of having the same fees for human and animal drugs, particularly when compliance and enforcement activities for veterinary products (including compounding) are not given a similar priority and currently issued DELs are putting the limitation of “veterinary drugs only” when issued.
- Veterinary drug regulatory service fees proposed should not be aiming for 90% cost recovery since it does not recognise the social benefit of these products or market size. The Canadian animal health product regulatory programme must be conducive to registration of new products if we are to be able to maintain animal welfare and human safety. The regulatory programme in Canada has significantly improved performance standards which has made it a favourable market; however, the proposed fees will be a barrier and will negatively affect the improvements made.
- Phase-in of increased fees over a two-year period in an industry this small will have a detrimental effect on bringing new products to the Canadian market. The generic pathway will also be compromised, leaving concerns with pricing and availability of drugs.
- To ensure a win-win solution for the veterinary drug programme, manufacturers, veterinarians, animal owners and the Canadian public CAHI would propose the following:
  - That the veterinary fee schedule be modernised, inclusive of current guidance, to incentivise availability of licensed products in a small market. This is particularly important for supplementary submissions, potential RCC reviews, niche products and MUMS products.
  - An initial compounded increase of 2% be implemented for veterinary drug service fees to reflect the fact that no increases were made in 2011 followed by annual CPI increases thereafter.

To ensure a robust animal health industry in Canada, the CAHI is advocating for change in the proposed fees. Animal health products contribute to the health and welfare of our food and companion animals and to food safety in the case of production animal drug.

#### APPENDIX 1: ANALYSIS OF THE CURRENT CANADA DIN PORTFOLIO AND THE POTENTIAL IMPACT TO NEW DRUG REGISTRATION AND LIFE CYCLE MANAGEMENT

The potential impact to the proposed fee increases was assessed using 2016 full year sales data as recorded by Impact Vet. Analysis of 676 Canadian veterinary DIN products that have 2016 sales of greater than \$15k was completed to demonstrate the percentage of products that will support initial registration and regulatory maintenance using the proposed fee structure.

Sales for 58% of the current livestock (production animal) products will not support a new registration, while 52% of companion animal product sales will not support introduction to the Canadian market. If innovation costs of 5% of the total R&D costs are included in the calculation, 79% of the livestock products (74% for companion animal) fall below the financial threshold to support product registration and launch in Canada.

Evaluation of the impact on maintenance and product life-cycle management demonstrates that sales for 40% of the current products in Canada will not support additions of new claims and annual licensing fees.

Species	File Type	Product Description	Third year sales to cover new reg fees	% of products in Canada that are below sales threshold (Impact Vet Data)	Third year sales to cover reg fees and R&D costs	% of products in Canada that are below sales threshold (Impact Vet Data)
Livestock	NDS	Livestock WO MFA Launch	250k	58%	640k	79%
		MFA Launch		21%		31%
Livestock	SND & NC	Livestock WO MFA Maintain	136k	40%	186k	50%
		MFA Maintain		14%		17%
Companion	NDS and NC	Prescription, Parasiticide	199k	52%	589k	74%

#### Assumptions for the Return on Investment Assessment:

- 676 pharmaceutical products commercialized in Canada were evaluated, with 234 products with sales of less than \$15k excluded from the analysis. The products included in the analysis were confirmed to be DIN products listed in the Compendium of Veterinary Products.
- Canadian sales are 5% of the global total so this percentage was applied to expected return on innovation investment.
- The registration fee return on investment was spread over a 3 year period, and based on full third year sales to cover one third of the registration and annual fees.
- Innovation costs were based on the USA Animal Health Institute's industry average.
- Current registered products utilize compendial grade active ingredients.
- Existing products will have two product changes per year and use non-compendial grade active ingredients.
- Product margin for a new product is expected to be above 60% to support a launch. Older products may have lower margins, but the goal is greater than 50%.

Three product registration activities were analyzed:

1 – Livestock product registration; 2 – Livestock product change (new claim or manufacturing site change); and, 3 – Companion Animal Product Launch.

#### Example 1: Registration of New Livestock Product

Registration Fees:  $139 + 174 + 29 = \text{CA\$}342,000$

Annual Maintenance Fee Estimate = CA\$36,000

5% of R&D Estimate for Canada = CA\$1.95 Million spread over 5 years for ROI = \$390,000

Margin 60% (for new product)

Sales needed in year 3 =  $[\$342 + (\$36 \times 3)] / (3 \times 60\%) + \$390 = \$640\text{k}$

If no R&D costs are to be recouped:  $[\$342 + (36 \times 3)] / (3 \times 60\%) = \$250\text{k}$

**Example 2: to Maintain a Livestock Product**

Registration Fees for Addition of new Claim = CA\$96,000  
 Annual Maintenance Fees = CA\$36,000  
 5% R&D for Canada, \$250,000 for new claim = \$50k per year, over 5 years  
 Margin 50% for an existing product.  
 Ongoing sales needed (calculated 3 years out for claim) =  $[\$96k + (\$36 \times 3)] / (3 \times 50\%) + \$50k = \$186k$

**Example 3 Launching a Companion Animal Product**

Registration Fees:  $96 + 174 + 29 = \text{CA}\$299,000$   
 Annual Maintenance Fee Estimate = CA\$20,000  
 5% of R&D Estimate for Canada = CA\$1.95 Million spread over 5 years for ROI = \$390,000  
 Margin 60% (for new product)  
 Sales needed in year 3 =  $[\$299 + (\$20 \times 3)] / (3 \times 60\%) + \$390k = \$589k$   
 If no R&D costs are to be recouped:  $[\$299 + (\$20 \times 3)] / (3 \times 60\%) = \$199k$

**APPENDIX 2: POST NOC QUALITY DOCUMENT - CHANGES THAT CHALLENGE VETERINARY DRUG MARKET ACCESS FOR CANADA**

\*NOTE: This document is not an all-inclusive comparison and is being provided with this submission to highlight currently identified major inconsistencies in the Post-NOC Quality guidance that affect market access for veterinary drugs.

**Changes to Drug Substance (DS) manufacturing site (Change Nr 2):** The need for DS site changes will be driven by the economics of Regulation (GMP, addition to DEL) and inspection (data integrity) and many suppliers will be dropping out of supplying API for finished veterinary drug products. Each DS site addition triggers a DEL fee but also, due to VDD policies, additional charges that would not necessarily apply in other jurisdictions.

Filing revisions for DS is a challenge for products with DS that were registered in the past. As we move to make the file compliant by adding the manufacturing information, or if we want to add a new manufacturing site we run into extensive document requirements. In the past, DS were registered with minimal data since they were listed in Schedule B publications (i.e. USP, BP Vet, EP) DS synthesis is often proprietary manufacturing company property and if a Master File is not available for these sites registered decades ago companies don't have this information for previously registered suppliers. Consequently, registering a new DS supplier is automatically a Supplemental Change and challenges supply.

**Changes to Drug Product (DP) manufacturing site (Change Nr 27):** Cost recovery registration and DEL fees will increase the rationalization of manufacturing sites with consolidation to fewer sites to keep fees lower.

In support of a manufacturing site change, a validation report for 3 commercial size batches is required for Canada. This is unique to Canada as both the USA and EU can file with 1 executed commercial lot and a protocol and execute validation after approval. Why does VDD place validation as high risk for Canada when the GMP's require industry to meet the 3 lot validation requirement prior to commercialization? It would be ideal and in line with RCC if Canada would accept 1 executed full scale commercial lot at time of filing like the USA. If we must wait for the execution of 3 lots to file, we are put in line with countries that do not have a well-developed regulatory framework. In addition, there is a financial impact to the sponsor to execute 3 lots prior to submission. Three lots of drug product at a commercial scale could have value of over \$1 million and

may not have shelf-life to support commercialization at time of approval if packaged specifically for Canada.

**Changes to Closure System for Sterile Products (Change Nr 40):** changes such as these would be occurring downstream of site changes.

All changes for sterile products are shifting to supplements. This is challenging supply of animal drugs to the Canadian market as the USA gains approvals in a much faster timeframe. Also, the USA process does not charge a fee unless a Supplemental Application (ANADA or NADA) is required.

If there are no changes to materials and suitability data are available (e.g., extractable/leachable testing, permeation testing) would VDD consider changing this to an NC. This allows for review but aligns the time more closely to the USA CBE path?

**Change or addition of a Test Site (Stability or Release) (Change Nr 27):** site rationalization will again result in consolidation of testing sites in order to keep fees lower.

Addition of a test location falls under GMP oversight and we must add each test site to the DEL and have agreements in place. The USA does not require that test sites be registered within a product dossier. The Post NOC Human DS and DP Test site requirement is a Level IV Annual Notification. With all of the DEL revisions, why does VDD mandate a Pre-Approval NC for addition of a test site for both DS (Change 2) and DP (change 27)? Compliance to the DEL and GMP requirements ensure adding a new test site is low risk as aligned with the human path. Now that Vet API will require GMP and DEL listing, the risk aligns with the human DS and DP test site change risk and should be considered for the AN path.

**APPENDIX 3: COMPETITIVENESS OF LICENSED VERSUS COMPOUNDED VETERINARY DRUGS RELATIVE TO THE NEW SERVICE FEE PROPOSAL**

The proposed fee increases promote the competitive advantage of compounded veterinary drugs over Health Canada licenced innovator and generic veterinary drugs.

The recent veterinary drug updates to the Food and Drug Regulations with respect to antimicrobial resistance finally introduced the requirement for veterinarians or pharmacists importing antimicrobials for compounding to hold a Drug Establishment Licence and report quantities of API imported to Canada. While this requirement was a first step to bringing manufacturing under the guise of compounding to an appropriate level of regulatory oversight, the proposed user fees further advantage compounders in the veterinary drug market place.

Please note that we are not discussing compounding in the sense of preparing a small amount of customized drug product for a single patient or a small group of patients. Our concern is compounding as unlicensed manufacturing for food animals, examples we are presently aware of would include:

- Colistin sulfate powder (colistin sulfate has never been licenced for administration to food animals in Canada)
- "Florfenicol" soluble powder (was actually chloramphenicol according to laboratory tests)
- Trimethoprim Sulfadiazine powder ("compounded" in Quebec, sold in Manitoba)
- Lincomycin soluble powder (exact copy of licenced



- pioneer and generic)
- Tetracycline HCl soluble powder (sold to dairy farmers without instructions for use)

Why does the ability to “compound” provide such a large competitive advantage? An example of a common regulatory maintenance activity required of DIN holders quantifies that advantage:

### Change of API Manufacturer

The change of and API manufacturer is one of the most common regulatory activities in veterinary drugs today.

Supplier changes are driven by:

- Regulatory activities:** regulatory activities causing supplier changes ranging from GMP non-compliance on inspection by advanced economy regulatory authorities (EU, USA FDA) to environmental permitting issues in the supplier's home country are forcing changes in the supplier base.
- Economics:** increasing restrictions on use of some APIs in major markets are causing some suppliers to abandon products as uneconomic.
- Demands for additional characterization of APIs:** VDD (and other regulators) demand up to date characterization of APIs and their impurities. The additional testing activities to develop a DMF are causing some suppliers to abandon products as uneconomic.

The need to maintain licensable suppliers will lead to very different expenditures for licenced and unlicensed manufacturers.

### 1. Change in Compendial API Supplier (non-sterile) as of April 01, 2019

Fees to Make the Change	Compounder	Manufacturer
Add new supplier to DEL (foreign site)	\$900.00	\$900.00
Chemistry & manufacturing for 1 dosage form	\$0.00	\$24,200.00
Continuing Fees to Market Licenced Product	Compounder	Manufacturer
Drug Right to Sell	\$0.00	\$4,587.00
<b>Total Fees to Maintain Product in Compliance with HC</b>	<b>Compounder</b>	<b>Manufacturer</b>
	<b>\$900.00</b>	<b>\$29,687.00</b>
Internal Costs to Make the Change	Compounder	Manufacturer
API cost – 3 lots + testing	Not required	\$15,000.00
Process Validation – 3 lots manufacturing and testing	Not required	\$30,000.00
Stability Study – 2 VICH conditions – 3 lots for 24 months	Not required	\$15,000.00
Low temperature (freezing) stability	Not required	\$2000*
Submission Preparation & report costs	Not required	\$5000.00
<b>Total Internal Costs</b>	<b>Compounder</b>	<b>Manufacturer</b>
	<b>\$0</b>	<b>\$67,000.00</b>
<b>Total Cost to keep product on the market</b>	<b>Compounder</b>	<b>Manufacturer</b>
	<b>\$900</b>	<b>\$96,687.00</b>

\* VDD frequently asks for “Do Not Freeze”, even on labels of solid dosage forms if data not submitted.

### 2. Change in Non-Compendial API Supplier (non-sterile) as of April 01, 2019

Fees to Make the Change	Compounder	Manufacturer
Add new supplier to DEL (foreign site)	\$900	\$900
Chemistry & manufacturing for change in source of non-compendial medicinal ingredient or its manufacturing process.	\$0	\$24,200
Chemistry & manufacturing for 1 dosage form		\$24,200
Continuing Fees to Market Licenced Product	Compounder	Manufacturer
Drug Right to Sell		\$4,587
<b>Total Fees to Maintain Product in Compliance with HC</b>	<b>Compounder</b>	<b>Manufacturer</b>
	<b>\$900</b>	<b>\$53,887</b>
Internal Costs to Make the Change	Compounder	Manufacturer
API cost – 3 lots + testing	Not required	\$15,000.00
Process Validation – 3 lots manufacturing and testing	Not required	\$30,000.00
Stability Study – 2 VICH conditions – 3 lots for 24 months	Not required	\$15,000.00
Low temperature (freezing) stability	Not required	\$2000*
Submission Preparation & report costs	Not required	\$5000.00
<b>Total Internal Costs</b>	<b>Compounder</b>	<b>Manufacturer</b>
	<b>\$0</b>	<b>\$67,000.00</b>
<b>Total Cost to keep product on the market</b>	<b>Compounder</b>	<b>Manufacturer</b>
	<b>\$900</b>	<b>\$120,887.00</b>

### APPENDIX 4: COMPARISON OF SERVICE FEES FOR REGULATORY REVIEW OF VETERINARY DRUGS – CANADA: AUSTRALIA

Canadian Category Description	VDD Current	VDD - Year 1	APVMA (40% CR)	Comments
1 Novel non-compendial API (never approved); 1 claim; 1 dosage form; 1 species (companion animal)	\$25,660 (MCED: 4840+4840; CED: 15980)	\$128,300 (MCED: 24200 + 24200; CED: 79900)	AU\$39,950 (Item 2 application with modules 1, 2.1, 3.1, 4, 5.1, 7.3, 8.1, 11.2, 12)	
2 As #1 but for food-producing animal (using lowest HSD category)	\$47,450 (MCED: 4840+4840; CED: 15980; HSD 21790)	\$237,250 (MCED: 24200 + 24200; CED: 79900; HSD 108950)	AU\$94,915 (Item 2 application with modules 1, 2.1, 3.1, 4, 5.1, 6.2, 7.1, 8.1, 11.1, 12)	
3 Well-known compendial API; 1 claim; 1 dosage form; 1 species (companion animal)	\$20,820 (MCED: 4840; CED: 15980)	\$104,100 (MCED: 24200; CED: 79900)	AU\$8,425 (Item 10 application with modules 1, 2.3, 8.2, 11.2, 12 + Item 17 application (API approval))	
4 As #3 but for food-producing animal (using lowest HSD category)	\$42,610 (MCED: 4840; CED: 15980; HSD 21790)	\$213,050 (MCED: 24200; CED: 79900; HSD 108950)	AU\$19,795 (Item 10 application with modules 1, 2.3, 5.4, 8.2, 11.1, 12 + Item 17 application (API approval))	
5 Generic: compendial active; 1 claim; 1 dosage form; 1 species (companion animal) - with bioequivalence waiver	\$4,840 (MCED: 4840)	\$24,200 (MCED: 24200)	AU\$7,445 (Item 6 application + Item 17 application (API approval))	
6 As #5 but with no bioequivalence waiver	\$7,740 (MCED: 4840; CED: 2900)	\$38,700 (MCED: 24200; CED: 14500)	AU\$8,030 (Item 10 application with modules 1, 2.3, 8.3, 11.2, 12+ Item 17 application (API approval))	
7 As #6 but for food producing animal (assumes abbreviated residue trial)	\$10,640 (MCED: 4840; CED: 2900; HSD 2900)	\$53,200 (MCED: 24200; CED: 14500; HSD 14500)	AU\$18,005 (Item 10 application with modules 1, 2.3, 5.4, 8.3, 11.3, 12+ Item 17 application (API approval))	
8 Supplemental to add additional claim to a product for food-producing animal species (same species/dosage)	\$12,590 (CED 12590)	\$62,950 (CED 62950)	AU\$3,690 (Item 14 application with modules 1, 8.2, 11.2, 12)	
9 Notifiable Change (example: site change for fabrication of finished dosage form - nonsterile)	\$1,300	\$6,500	If AU site: AU\$175 (Item 13A); If non-AU site AU\$4,295 (Item 14 application with modules 1,2,3,11.2,12)	
10 Not new drug DIN application	\$720	\$3,600	AU\$1,170 (Item 12)	Comparative based on label update to product grandfathered from State registration system (1996)
11 Investigational New Drug - unapproved product; non-compendial active; request for investigational efficacy protocol approval in food-producing animal (using lowest HSD category)	\$24,200 (4840+4840+14520)	\$121,000 (24200+24200+72600)	*AU\$35,867.50 (Tier 3 application with meeting; followed by Item 23 application with modules 1, 2.2, 3.2, 5.3, 7.3, 8.3, 11.1)	Comparative based on protocol reviewed under pre-application assistance with a meeting followed by a research permit request
12 Experimental Studies Certificate - approved product in companion animal; request for study to support indication in food-producing species	\$2,900	same	*AU\$15,265 (Item 23 application with modules 1, 3.2, 5.3, 7.3, 8.3, 11.1)	Comparative based on closest type of similar submission
13 Emergency Drug Request (food producing animal)	\$100	same	AU\$0 (Item 22 application (modular fee based on type of study being requested))	
Misc Fee reduction provision	Remission granted if fee is >10% gross revenue from the product(s) in first 3 years	\$10,000 first submission only	none	
Minor Use/Minor Species (MUMS)	As per fee reduction provision	none available	AU\$350 (If minor use permit for minor species use (no MUMS system))	
Annual DIN renewal	\$250 (or \$50 with fee reduction provision)	\$627 (no fee reduction provision)	AU\$430	
Annual levy on sales	---	---	0.63% 5000-1 million; 0.35% 1-5 million; 0.25% >5 million	
Time of payment	10% at screening; 40% after screening; 50% after review 1	100% when submitted	AU\$710 at filing; balance after administrative check (approx. 30 days)	

## APPENDIX 5: COMPARISON OF SERVICE FEES FOR DRUG ESTABLISHMENT LICENSING OF VETERINARY DRUGS CANADA: AUSTRALIA

	Canadian Category Description	HC Current	HC - Year 1	APVMA	Comment
1	Small import business: importer activity, 2 dosage forms, 2 foreign sites	<b>\$4,950</b> (2500+1250+1200)	<b>\$33,545</b> (31,745+1800)	<b>AU\$1,000</b> each foreign site imported from (regardless of # of products from that site)	If multiple sites involved (i.e. fabrication, testing, alternative mfg site) you are charged \$1000 for each site
2	Sterile fabricator; 2 dosage forms	<b>\$12,000</b> (6000+3000+3000)	<b>\$41,114</b>	<b>AU\$7,500</b> (and AU\$900 application fee)	Same GMP licence held by packagers / labellers and analytical labs as well
3	Non-sterile fabricator; 2 dosage forms	<b>\$9000</b> (\$6000+3000)	<b>\$30,481</b>	<b>AU\$5,000</b> (and AU\$900 application fee)	Same GMP licence held by packagers / labellers and analytical labs as well
4	Packager / labeller; 2 dosage forms	<b>\$6,000</b> (4000+2000)	<b>\$5,942</b>	<b>AU\$7,500</b> sterile <b>AU\$5,000</b> non-sterile (and AU\$900 application fee)	
5	Distribution / wholesaling	<b>\$1,500</b>	<b>\$9,851</b>	none	
6	Testing	<b>\$1,000</b>	<b>\$27,109</b>	<b>AU\$7,500</b> sterile <b>AU\$5,000</b> non-sterile (and AU\$900 application fee)	
7	Fee reduction provision	remission granted if fee is >1.5% gross revenue from the product(s)	none	50% reduction if wholesale value in previous year <AU\$50,000	

## REFERENCES

1. <https://www.cdc.gov/onehealth/basics/zoonotic-diseases.html>

**Jean Szkotnicki**

President of the Canadian Animal Health Institute (CAHI), a trade association representing companies that develop and manufacture pharmaceuticals, biologicals, feed additives and pesticides used to support the health and well-being of our companion and food animals.

In her capacity as President, Jean works with CAHI members to develop Institute policy and strategic directions. Liaison and communication activities with regulatory authorities, producer groups, veterinary associations, research institutions and the media are also important in her role.

Jean has both BSc (Agr) and MSc degrees from the University of Guelph, Guelph, Ontario. She was inducted into the Canadian Agricultural Hall of Fame in 2017.

Email: [jszk@cahi-icsa.ca](mailto:jszk@cahi-icsa.ca)