July 25 2019

CAHI Comments on the Health Canada Revised Cost Recovery Regime for Veterinary Drugs

The Canadian Animal Health Institute (CAHI) welcomes the opportunity to comment on the revised service fees for veterinary drugs that are to be introduced April 1st 2020. We understand the new fees are thought to better reflect the value of Health Canada services provided to users and for continuous improvement. However, CAHI believes the new fees do not reflect the true business realities facing the veterinary drug sector. Therefore, our comments will focus on ideas which share in the regulatory direction recommended by Canada's Economic Roundtable for Agri-Food to have, *"an agile regulatory system that supports innovation, provides certainty to industry, and protects health and safety."* In a recent letter to CAHI, Health Canada senior management says it will, *"continue to improve the delivery of our regulatory services, allowing us to meet the needs of Canadians and the healthcare system, while remaining competitive with other international regulators.*"

As we move forward with implementation of the new fee structure, there needs to be an acknowledgement that fees for our veterinary drug regulatory program need to be competitive relative to market size in comparison to other international regulatory programs. To do this, we may need to stop performing a number of the regulatory activities we currently do.

Set out below is CAHI data, analysis and comments related to: 1) the business reality of veterinary drugs in Canada; 2) analysis of how the new veterinary drug fees are not competitive in relation to market size; and 3) eight (8) recommended next steps.

1. THE BUSINESS REALITY FOR VETERINARY DRUGS IN CANADA

The Canadian animal health business is only 2.5% of the global animal health market. The human pharmaceutical industry in Canada, which benefits from publicly funded provincial drug programs, 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 and regulatory maintenance. Drug innovation costs are C$29 million and C$39 million for companion and livestock drugs, respectively, and the return on investment is not realized for 3 – 7 years.

Analysis of the incoming service fees for veterinary drug review, drug establishment licenses (DEL), and maintenance by one Canadian veterinary drug company found that if implemented as is:

- sales for 58% of the current livestock products will not support a new registration due to review, DEL and maintenance fees; and
- 52% of companion animal product sales will not support being introduced and/or maintained in the Canadian market for the same reasons.
- If innovation costs of 5% of the total research and development (R&D) costs are included in the calculation:

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- 79% of the livestock products; and
- 74% for companion animal

fall below the financial threshold to support product registration and launch in Canada (Appendix 1).

Further analysis was done using Veterinary Purchasing (VP) buying group data. The company is a St. Mary's, Ontario based business owned solely by licensed veterinarians to purchase animal health products and hospital supplies for distribution to its members. VP mined all its 2017 sales data to help CAHI and its members assess the impact of the new service fees for the veterinary drugs it buys and distributes. In total, VP stocks and distributes 1,026 veterinary drug products to veterinarians, most of which are based in Ontario.

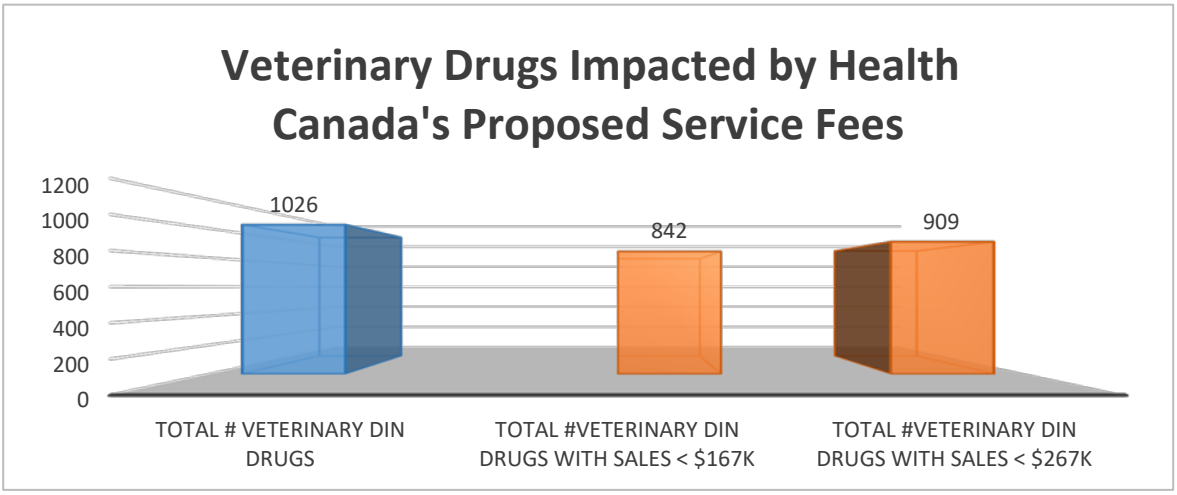
CAHI analysis indicates that with the new service fees, a veterinary drug would have to generate a minimum of $500 - 800K in annual sales to warrant re-registration and maintenance. VP's Ontario sales represent approximately one third (1/3) of veterinary drug sales across Canada. Using this information, the representative Ontario annual sales values needed for re-registration, DEL and maintenance fees of a veterinary drug would be in the range of $167K to $267K.

Using the above criteria:

- **842 (82%) of the veterinary drugs products have sales of less than $167K**
- **909 (89%) of the veterinary drug products have sales of less than $267K**

The unintended consequence of the new fee schedule, as outlined above, is to change a product lifecycle such that a drug sponsor would no longer seek supplementary claims or additional species as a means of managing regulatory costs. This information clearly demonstrates the need for drastic adjustments to the delivery of the veterinary drug program which Health Canada administers.

Losing 80 to 90% of the registered products would be a huge step backward resulting in more crude, compounded medications and more off label use, and, frankly poorer health care for both food and companion animals and higher risks to the public.



2. THE NEW VETERINARY DRUG FEES ARE NOT COMPETITIVE RELATIVE TO MARKET SIZE

In 2017 the gross value of Australian agricultural production was estimated to be AU$62.8 billion while Canada was just shy of that mark, at AU$58.6 billion.[i] Appendix 2 is an analysis conducted by CAHI of the veterinary drugs review and DEL process for selected submission types. Generally, Health Canada is proposing to charge significantly more in fees than Australia, which is of a similar market size to Canada. Set out below are two tables highlighting the key findings that are reviewed in more depth in Appendix 2.

Table 1: Key Findings of the CAHI Review of Health Canada's New Veterinary Drug Fees in Comparison to those of the APVMA

Canadian Category Description	**VDD Fees as of April 2026**	**Australia Pesticide and Veterinary Medicines Authority (APVMA) Fees, Feb. 2018***
Novel, non-compendial Active Pharmaceutical Ingredient (API): 1 claim, 1 dosage form, 1 species, companion animal	$87,245	$39,950
Same as above - food animal	$161,331	$94,915
Well-known, compendial API: 1 claim, 1 dosage form, 1 species food animal	$144,875	$19,795
Generic, compendial API: 1 claim, 1 dosage form; 1 species; no bioequivalence waiver; food animal	$36,178	$18,005

**The APVMA is currently working on developing and implementing a new CRIS (Cost Recovery Impact Statement) during 2019/2020. It is our understanding that this happens every 5 years. The last fee increases were implemented in 2014, with a second tranche in 2015.*

Table 2: Key Findings of the CAHI Review of Health Canada's New DEL Fees in Comparison to those of the APVMA

Canadian Category Description	**Health Canada DEL Fees as of April 2026**	**APVMA Fees, Feb. 2018***
Small import business, importer activity: 2 dosage forms, 2 foreign sites	$34,216	$1,000
Sterile fabricator: 2 dosage forms	$40,198	$7,500

**The APVMA is currently working on developing and implementing a new CRIS (Cost Recovery Impact Statement) during 2019/2020. It is our understanding that this happens every 5 years. The last fee increases were implemented in 2014, with a second tranche in 2015.*

As noted, 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 in order 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 seeing a return on investment.

This situation will:

- Negatively impact both products coming into, and staying in, the Canadian market;
- Mean fewer new products, supplementary new drug submissions, minor use/minor species (MUMS) and Canada-United States Regulatory Cooperation Council (RCC) submissions based on the new fee structure; and
- Result in higher risk and illicit market due to illegal importation and compounding of veterinary drugs to meet animal health and welfare needs.

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 due to higher illegal importation and compounding of veterinary drugs.

In addition to the new fees outlined above, veterinary drug companies are as of 2019 having to meet new Good Manufacturing Practices (GMP) requirements for API. This activity comes with an even higher cost to the animal health industry. **Our analysis shows that for the 89% of our products that would have sales of less than $267K, the DEL and maintenance costs erode that margin by a further 20 – 25%.** This will result in fewer veterinary drug registrations and fewer veterinary drugs being maintained in Canada even though non-GMP APIs have been used in many veterinary products without demonstrated risk since 1963.

3. RECOMMENDED NEXT STEPS

The challenge ahead is to have regulatory fees competitive relative to market size so that Canadian animal owners have access to the same health management tools as other developed countries. CAHI appreciates the fact that Health Canada provided the veterinary drug sector a seven (7) year lead-in to the new fees and a lower payment regime for veterinary drug reviews versus human, but we think even bolder steps need to be taken to achieve the competitiveness goal.

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

1. **Discontinue Companion Animal Product Reviews and Product Life Cycle Management for Veterinary Drugs Licensed by Trusted Regulators and Substitute with an Administrative Fee for Acceptance of the Submission** – The review of veterinary drugs for companion animals does not support the healthcare system and pets in the developed world generally are cared for similarly between countries.

Furthermore, Canada does not regulate pet foods, some of which make quasi drug claims, so why should it regulate veterinary companion animal drugs the extent it does? It is the recommendation of the CAHI that Canada accept foreign reviews and maintenance decisions from trusted regulatory authorities (e.g. USA, EU, UK) for companion animal drugs. Quality standards would need to be aligned with the trusted regulatory authority requirements and companies selling companion animal products would need to attest to meeting those standards.

2. **Modernize Manufacturing and Quality Reviews Through Use of Foreign Decisions by Trusted Regulatory Authorities** – As mentioned earlier Canada is only 2.5% of the global market. Consequently, products most often get manufactured for the global market and not just solely for the Canadian market. To ensure product availability in the Canadian market there is a need for alignment with our trusted regulatory authorities and the standards they administer. Again, acceptance of foreign reviews from trust regulatory authorities would help to build in efficiencies and cost savings into the regulatory fee process and support product availability.

3. **Modernize Clinical Efficacy Reviews Through Use of Foreign Decisions by Trusted Regulatory Authorities** – Expanding on the above recommendations foreign decisions should be used to build in review efficiencies for species such as poultry and swine, which have relatively standardized production practices in the developed world.

4. **Modernize the Fee Structure to have Incentives for Minor Use and Minor Specie (MUMS) Submissions** – Any fee structure must include MUMS submissions. MUMS products are offered at a cost to the animal health companies as a service to veterinarians and animal owners. The current fee structure does not support companies in developing a business case to accommodate MUMS; in fact, the schedule does not even recognize MUMS as veterinary drugs. Presently these fees are considered on a case-by-case basis and are not transparent or consistent. We would recommend an 80% reduction in review and maintenance fees for MUMS products due to the limited sales of these products and with an assumed lower risk due to the small volumes used.

5. **Modernize the Fee Structure for Joint and Shared Reviews** – For the joint and shared reviews CAHI recommends a reduction in the review fees by 50%. Joint and shared reviews are important foundations to veterinary drug alignment of labels between countries, availability of product for animal owners and supportive of trade in food animal products because farmers have access to the same health management tools.

6. **Incentives for Small to Medium Sized Companies (SME) Need to be Expanded** – Any veterinary drug sponsor that is a SME, regardless of whether it is an affiliate or not since all companies and/or divisions must have business accountability, needs to be encouraged to bring new product to the Canadian market. Canadian based companies should be encouraged to do R&D using Canada as the first registration that could be recognized elsewhere.

7. **Incentives for Alternatives to Category I, II, and III Medically Important Antimicrobials** – To support the reduced need for antimicrobials in veterinary medicine there should be a 50% reduction in the review fees for alternatives to antimicrobials.

8. **Component-Based Fee Structure Needs to be Maintained –** CAHI supports the component-based fee structure presently in place since it more accurately reflects the true cost to government for the services

it delivers and is closely aligned with the EU and Australian fee structures for veterinary drug regulatory services.

In closing CAHI trusts that there will be opportunity to have meetings with Health Canada officials to discuss the above eight points. As per the Economic Roundtable for Agri-Food we think the discussion should be made possible through a government industry committee. The Canadian Animal Health Product Regulatory Advisory Committee (CAHPRAC) would be a useful body to facilitate a regulatory modernization discussion. We believe the modernization changes outlined above for Canada's veterinary drug program will help to create and maintain good jobs for the middle class and build economic prosperity that will ensure a safe and bright future for all Canadians and the animals we care for.

[i] Alex Sampson, Canadian agriculture: On par with Australia with room to differ, The Weekly Times, November 12, 2017. https://www.weeklytimesnow.com.au/agribusiness/decisionag/canadian-agriculture-on-par-with-australia-with-room-to-differ/news-story/7505adfd0fd3ac15cabca27d84c03149. Accessed July 19, 2019.

APPENDIX 1: ANALYSIS OF THE CURRENT CANADIAN VETERINARY 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 drug 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 food animal products and 74% of the companion animal products 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	SNDS & NC	Lifestock 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 = 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 x3)] / (3 x 60%)] + $390 **= $640k**

If no R&D costs are to be recouped: [$342 + (36x3)] / (3 x 60%) = $250k

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 x 3)] / (3 x50%)] + $50k = **$186k**

Example 3 Launching a Companion Animal Product

Registration Fees: 96 + 174 + 29 = 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 x3)] / (3 x 60%)] + $390k **= $589k**

If no R&D costs are to be recouped: [$299 + ($20 x3)] / (3 x 60%)] **= $199k**

Appendix 2.A - Veterinary Drug Fees versus APVMA Fees

						APVMA (40% CR); 1 AU$=0.93 CA$
	Canadian category description	**HC Prior**	**HC Current (as at April 2019 2.2% increase)**	**HC Fiscal Year 1 (as at April 2020)**	**HC Fiscal Year 7 (as at April 2026)**	***Not updated from Previous summary during consultation***
1	novel non-compendial API (never approved): 1 claim; 1 dosage form; 1 species (companion animal)	**$25,660** (MCED: 4840+4840; CED: 15980)	**$26,224.52** (MCED: 4946.48 + 4946.48; CED: 16331.56)	**$32,717** (MCED: 6171 + 6171; CED: 20375)	**$87,245** (MCED: 16456 + 16456; CED: 54333)	**AU$39,950** (Item 2 application with modules 1, 2.1,3.2,4,6.2,7.3,8.1,11.1, 12
2	as #1 but for food-producing animal (using lowest HSD category)	**$47,450** (MCED: 4840+4840; CED: 15980; HSD 21790)	**$48,493.90** (MCED: 4946.48+4946.48; CED: 16331.56; HSD 22269.38)	**$60,500** (MCED: 6171 + 6171 CED: 20375 HSD: 27783)	**$161,331** (MCED: 16456 + 16456; CED: 54333 HSD: 74086)	**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)	**$21,278.04** (MCED: 4946.48; CED: 16331.56)	**$26,546** (MCED: 6171; CED: 20375)	**$70,789** (MCED: 16456; CED: 54333)	**AU$8,425 (Item 17: $3,155; Item 10: $5,270)** 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)	**$43,547.42** (MCED: 4946.48; CED: 16331.56; HSD 22269.38)	**$54,329** (MCED: 6171; CED: 20375; HSD: 27783)	**$144,875** (MCED: 16456; CED: 54333; HSD: 74086)	**AU$19,795 (Item 17: $3,155; Item 10: $16,640)** modules 1, 2.3,5.4,8.2,11.1, 12 + Item 17 application (API approval)

Appendix 2.A - Veterinary Drug Fees versus APVMA Fees

	Canadian category description	HC Prior	HC Current (as at April 2019 2.2% increase)	HC Fiscal Year 1 (as at April 2020)	HC Fiscal Year 7 (as at April 2026)	*Not updated from Previous summary during consultation*
5	Generic: compendial active; 1 claim; 1 dosage form; 1 species (companion animal) - with bioequivalence waiver	**$4,840** (MCED: 4840)	**$4,946.48** (MCED: 4946.48)	**$6,171** (MCED: 6171)	**$16,456** (MCED: 16456)	**AU$7,445 (Item 6: $4,290; Item 17: $3,155)**
6	as #5 but with no bioequivalence waiver	**$7,740** (MCED: 4840; CED 2900)	**$7,910.28** (MCED: 4946.48; CED 2963.80)	**$9,869** (MCED: 6171; CED: 3698)	**$26,317** (MCED: 16456; CED: 9861)	**AU$8,030 (item 17: $3,155; Item 10: $4,875)**(modules 1,2.3,8.3,11.2, 12+ Item 17 application (API approval)
7	as #8 but for food producing animal (assumes abbreviated residue trial)	**$10,640** (MCED: 4840; CED 2900; HSD 2900)	**$10,874.08** (MCED: 4946.48; CED 2963.80; HSD 2963.80)	**$13,567** (MCED: 6171; CED 3698; HSD 3698)	**$36,178** (MCED: 16456; CED 9861; HSD 9861)	**AU$18,005 (Item 17: $3,155; Item 10: $14,850)** 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)	**$12,866.98** (CED 12866.98)	**$16,053** (CED 16053)	**$42,807** (CED 42807)	**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**	**same**	**$1,658**	**$4,420**	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)

Appendix 2.A - Veterinary Drug Fees versus APVMA Fees

	Canadian category description	HC Prior	HC Current (as at April 2019 2.2% increase)	HC Fiscal Year 1 (as at April 2020)	HC Fiscal Year 7 (as at April 2026)	*Not updated from Previous summary during consultation*
10	not new drug DIN application	**$720**	**$735.84**	**$918**	**$2,448**	**AU$1,170** (Item 12)
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** (MCED: 4840; CED: 4840; HSD 14520)	**$24,200** (MCED: 4946.48; CED: 4946.48; HSD 14839.44)	**$30,855** (MCED: 6171; CED 6171; HSD 18513)	**$82,280** (MCED: 16456; CED 16456; HSD 49368)	***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
12	Experimental Studies Certificate (food-producing animal)	**$2,900**	**$2,963.80**	**$2,958**	**same**	***AU$15,265** Item 23 application with modules 1, 3.2,5.3,7.3,8.3,11.1 **comparative based on*
13	Emergency Drug Request (food producing animal)	**$100**	**$102.20**	**$102**	**same**	**AU$0** (Item 22 application (modular fee based on type of study being requested)
14	Veterinary Health Product notification	n/a	n/a	$486	$486	---

Appendix 2.A - Veterinary Drug Fees versus APVMA Fees

	Canadian category description	HC Prior	HC Current (as at April 2019 2.2% increase)	HC Fiscal Year 1 (as at April 2020)	HC Fiscal Year 7 (as at April 2026)	*Not updated from Previous summary during consultation*
15	fee reduction provision	remission granted if fee is >10% gross revenue from the product(s) in first 3 years	same	first pre-market submission fee waived for a drug on the "List of Drugs for an Urgent Public Health Need"; all fees waived for publicly funded healthcare institutions; all other fee deferrrals and mitigation eliminated;	same	
16	small business fee exemptions	---	---	first pre-market submission free for new small business (never previously filed in Canada); 50% mitigation on future pre-market submissions; 25% mitigation on right to sell fees	same	
17	MUMS	as per fee reduction provision	stakeholder consultation 2019?	not mentioned	not mentioned	**AU$350** if minor use permit (no MUMS system)

Appendix 2.A - Veterinary Drug Fees versus APVMA Fees

	Canadian category description	HC Prior	HC Current (as at April 2019 2.2% increase)	HC Fiscal Year 1 (as at April 2020)	HC Fiscal Year 7 (as at April 2026)	*Not updated from Previous summary during consultation*
18	Annual DIN renewal	**$250** (or $50 with fee reduction provision)	**$255.50**	**$312**	**$477**	**AU$430**
19	Annual levy on sales	---	---	---	---	0.63% 5000-1 million; 0.35% 1-5 million; 0.25% >5 million
20	Time of payment	10% at screening; 40% after screening; 50% after review 1	same	full pre-market fees at time of submission	same	**AU$710** at filing; balance after administrative check (approx 30 days)

Appendix 2.B - DEL Fees versus APVMA Fees

	Canadian category description	HC Prior	HC Current (as at April 2019 2.2% increase)	HC Fiscal Year 1 (as at April 2020)	HC Fiscal Year 7 (as at April 2026)	*APVMA 1 AU$=0.93 CA$ Not updated from previous summary during consultation*	*Comments*
1	Small import business: importer activity, 2 dosage forms, 2 foreign sites	**$4,950** (2500+1250+1200)	**$5.058.90** (2555+1277.50+ 1226.40)	**$12,245** (10715+765+765)	**$34,216** (32380+918+ 918)	**AU$1,000** each foreign site imported from (regardless of # of products from that site)	*if multiple sites involved (ie fabrication, testing, alternative mfg site) you are charged $1000 for each site*
2	Sterile fabricator: 2 dosage forms	**$12,000** (6000+3000+3000)	**$12,464** (6132+3066+306 6)	**$40,198**	**$41,937**	**AU$7,500** (and AU$900 application fee)	*same GMP licence held by packagers/labellers and analytical labs as well*
3	Non-sterile fabricator: 2 dosage forms	**$9,000** (6000+3000)	**$9,198** (6132+3066)	**$8,782**	**$31,091**	**AU$5,000** (and AU$900 application fee)	*same GMP licence held by packagers/labellers and analytical labs as well*
4	Packager/ labeller: 2 dosage forms	**$6,000** (4000+2000)	**$6,132** (4088+2044)	**$6,061**	**same**	**AU$7,500** - sterile; AU**$5,000** non-sterile (and AU$900 application fee)	
5	Distibution	**$2,500**	**combined with wholesaling**	**$4,835**	**$16,527**	none	
6	Wholesaling	**$1,500**	**$1,533.00**	**$1,933**	**$7,372**		

Appendix 2.B - DEL Fees versus APVMA Fees

	Canadian category description	HC Prior	HC Current (as at April 2019 2.2% increase)	HC Fiscal Year 1 (as at April 2020)	HC Fiscal Year 7 (as at April 2026)	*APVMA 1 AU$=0.93 CA$ Not updated from previous summary during consultation*	*Comments*
7	Testing	**$1,000**	**$1,022**	**$1,315**	**$5,002**	**AU$7,500** - sterile; AU**$5,000** non-sterile (and AU$900 application fee)	
8	Small business fee exemptions	---	---	25% mitigation on DEL fees	same		

Appendix 2.B - DEL Fees versus APVMA Fees

	Canadian category description	HC Prior	HC Current (as at April 2019 2.2% increase)	HC Fiscal Year 1 (as at April 2020)	HC Fiscal Year 7 (as at April 2026)	*APVMA 1 AU$=0.93 CA$ Not updated from previous summary during consultation*	*Comments*
9	Fee reduction provision	remission granted if fee is >1.5% gross revenue from the product(s)	same	first pre-market submission fee waived for a drug on the "List of Drugs for an Urgent Public Health Need"; all fees waived for publicly funded healthcare institutions; all other fee deferrrals and mitigation eliminated; DEL fees prorated quarterly for new applications	same	50% reduction if wholesale value in previous year <AU$50,000	