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FINAL REPORT: FEES FOR DRUGS AND MEDICAL DEVICES

May 2019

Canada

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

As the regulator responsible for helping Canadians maintain and improve health, Health Canada regulates human and veterinary drugs and medical devices by performing scientific evaluations of products before they are authorized for sale, monitoring these products once made available to Canadians and verifying compliance and non-compliance using tools such as inspections.

Budget 2017 granted the Minister of Health with new fee setting authorities that give the flexibility to fix and adjust fees in a timely way. The globalization of drug and medical device industries means that many products follow complex pathways through multi-step supply chains prior to reaching Canada. These new realities have changed the environment for regulating these products, increasing the complexity of regulatory work and creating new regulatory challenges for Health Canada. The new authorities ensure that fees are appropriately set, so that they better reflect actual costs and allow Health Canada to deliver more effectively on its regulatory programs. Under these authorities, Health Canada consulted with stakeholders from October 2017 to June 2018 to revise fees related to human drugs, veterinary drugs, and medical devices.

The development of the final fees follows extensive stakeholder engagement, and is a significant departure from the original fee proposal of October 2017. Stakeholder response generally focussed on the financial impact of the revised fees with some sectors highlighting specific challenges. For example, the veterinary sector raised concerns with the sudden increase of fees that had not changed since the mid-nineties, and the non-prescription sector questioned the level of effort for post market surveillance of their products compared to others.

Fees will be set at 50% to 100% of costs, and most will be phased in over four to seven years. Small business mitigation will be augmented, fees for new Drug Establishment Licences will be prorated based on when in the calendar year the application is made, and the Drug Right to Sell fee will be divided into three categories to represent the varying degrees of effort associated with disinfectants, non-prescription and prescription drugs. All fees will be adjusted annually by the Consumer Price Index starting April 1, 2021. Health Canada remains accountable for its regulatory services by ensuring that all fees have a performance standard. In the event that a performance standard is not met, Health Canada will remit 25% of the fee paid. Mitigation will be available to all publicly funded health care institutions, drugs on the Urgent Public Health Needs list or Canada's Access to Medicines Regime.

Health Canada will be engaging with stakeholders annually to discuss issues germane to fees including performance, costs and program efficiencies.

The revised fees will be implemented April 1, 2020, as published in the *Canada Gazette*, Part II on May 29, 2019.

SECTION I: INTRODUCTION

Health Canada introduced fees for regulatory services in the mid-nineties to partially recover the costs associated with some of its regulatory activities. In 2011, Health Canada updated fees for human drugs and medical devices. However, fees for veterinary drugs have not been updated since their inception in the mid-nineties.

Budget 2017 granted the Minister of Health authorities to fix fees via Ministerial Order under the *Food and Drugs Act*. Health Canada is now exercising these new authorities to amend fees related to human drugs, veterinary drugs, and medical devices. Fees related to food and human natural health products are not part of this fee update.

Like many other jurisdictions, including the United States, Australia and Europe, Health Canada charges fees for regulatory services for drugs and medical devices. Some international regulators have set their fees at up to 90% to 100% of their costs, and regularly update their fees. Currently, Health Canada fees are not reflective of the costs to deliver its regulatory programs. New regulatory challenges stemming from increasingly complex submissions; greater risks from counterfeit or contaminated products; and increased volume of products imported into Canada means Health Canada must adapt in order to continue maintaining the effective and efficient delivery of its regulatory activities.

Although Health Canada has remained internationally competitive in meeting performance standards, these realities have increased the costs of doing business and placed pressure on the regulatory system. Health Canada began consultations with stakeholders in October 2017 and applied the following principles in updating its fees:

- **Be Reasonable and Fair**: recognizing that industry needs to pay its fair share and reduce the burden on taxpayers, fees have been set reasonably and are being phased-in
- **Minimize Impact on Small Business**: fees should not deter small businesses from doing business in Canada
- **Apply Appropriate Mitigation**: fees should be reduced or exempted in explicit circumstances to support the health care system
- **Make Fee Increases Gradual and Predictable**: revised fees will be phased-in over multiple years
- **Ensure Accountability**: remaining transparent and accountable to stakeholders through annual reporting and annual engagement is key to developing an agile and responsive fee strategy

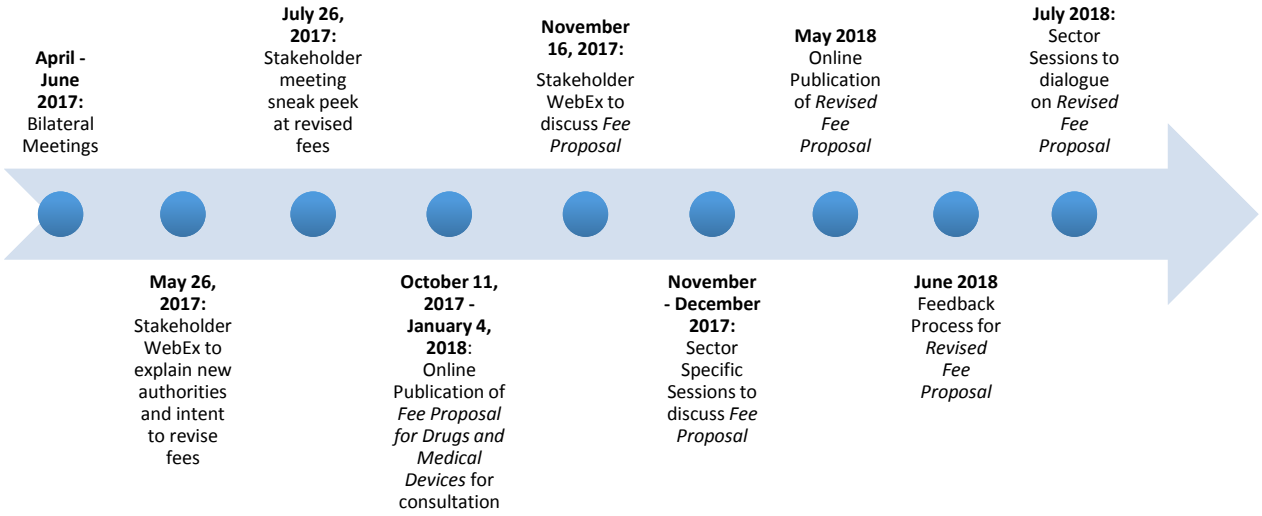
This document presents a summary of stakeholder comments and concerns, Health Canada's responses and the Final Fees for Drugs and Medical Devices which come into force April 1, 2020.

SECTION II: STAKEHOLDER ENGAGEMENT

Health Canada started engaging with stakeholders in spring 2017 to inform them of the new modernized approach the Department was taking on cost recovery for drugs and medical devices. In October 2017, Health Canada published its Fee Proposal for Drugs and Medical Devices (Fee Proposal). The Fee Proposal outlined amendments to fees for human drugs, veterinary drugs, and medical devices for three fee lines: Evaluation Fees, Establishment Licensing Fees, and Right to Sell Fees.

Although stakeholders generally support Health Canada's position on cost recovery, many of them shared comments on the fee increases, insufficient mitigation measures and lack of small business provisions, and lack of predictability for annual adjustments. Health Canada considered all stakeholder comments and in May 2018, published the Revised Fee Proposal for Drugs and Medical Devices (Revised Fee Proposal). The Department provided stakeholders an opportunity to submit feedback on the Revised Fee Proposal.

Overall, Health Canada hosted 32 stakeholder engagements and consulted with hundreds of stakeholders in person, online, through teleconferences and WebEx sessions.



SECTION III: FINAL FEES

The evolution of the fee proposal from its inception to its finality is depicted below. This includes themes that apply across products and fee lines and comments on specific fee lines.

While outside the scope of the proposal to revise fees, some stakeholders shared their concerns regarding the new authorities granted to the Minister to fix fees, and Health Canada's exemption to the *Service Fees Act.* All fees fixed under the *Food and Drugs Act* will continue to follow regulatory development pathways and requirements, including consultation, transparency and accountability.

FEE SETTING

Fee Proposal	Stakeholder Views	Final Fees
Pre-market Evaluation: Drugs / Devices: 90% of costs Vet: 75% year 1, 90% year 2 **Right to Sell:** 90% for all products **Establishment Licences:** 100%; one fee to be charged per establishment, regardless if Human or Veterinary Drug activities	Fee setting ratio is too high (90% to 100%); would like Health Canada to maintain its fee setting ratio or increase them gradually Would like Health Canada to create a tiered fee structure for the Drug Right to Sell fee The proposed fees for Establishment Licences, especially for veterinary drugs are too high too fast	**Pre-market Evaluation:** Drugs / Devices: Fees set at 75% of costs (phased in over four years) Vet: Fees set at 50% of costs (phased in over seven years) **Right to Sell:** Fees set at 67% of costs for all products (human and veterinary drug fees phased in over four years) Drug Right to Sell: 3 tiers of fees: 1. Prescription 2. Non-Prescription 3. Disinfectants **Establishment Licences:** Fees set at 100% of costs; one fee to be charged per establishment, regardless if Human or Veterinary Drug activities (fees for human drugs phased in over four years, veterinary drugs over seven years)

Presently, Health Canada recovers 43% of its costs for regulatory activities from industry, while the remaining costs are covered by Canadian taxpayers, compared to other jurisdictions like Australia and the European Medicines Agency that recover 100% of their costs leaving no burden on their tax payers. The Fee Proposal saw Health Canada proposing all fees be set at 90% to 100% of costs as this approach aligns with other international regulators. Although stakeholders acknowledged that fees need to be updated, many were concerned with how much the fees were increasing by, especially the increase in the Drug Right to Sell fee. Stakeholders recommended that Health Canada maintain its current fee setting ratios or use a phased-in or staggered approach for the proposed fee changes to allow industry time to adjust to the increases, or establish fees based on the Canadian market size. Some stakeholders raised concerns about fee increases for products that will soon be regulated under the Self Care Framework and would prefer fees for these products remain unchanged until that time.

Health Canada responded to stakeholders' concerns by phasing-in fees over multiple years (four years for all revised fees except veterinary pre-market evaluation and veterinary establishment licence fees with a seven year phase in; all new or reduced fees to be charged the full amount in year one) as well as reducing the fee setting ratios for most fee lines.

To respond to concerns on the Drug Right to Sell fee, this fee has been tiered to appropriately reflect the lower level of effort required for regulatory oversight related to disinfectants and over-the-counter products as compared to prescription drugs. Because of this recalculation, the fee originally consulted on for prescription drugs ($4,587) now represents 67% of costs. Therefore, Health Canada chose to maintain the proposed fee for prescription drugs even though the revised cost was higher for this category of drugs, and applied the same fee-setting ratio for all products, including medical devices and veterinary drugs.

Health Canada noted stakeholders' concerns about future products being regulated under the Self Care Framework, however, fees apply to current activities. Once the Self Care Framework is in place, Health Canada will review and update its fees accordingly and stakeholders will be consulted appropriately.

COSTING

Fee Proposal	Stakeholder Views	Final Fees
Treasury Board of Canada Secretariat's Guidelines on Costing to determine costs	Concerned with costing methodology and transparency	Costing document detailing methodology Tiered Drug Right to Sell fee

Stakeholders expressed concern with the methodology utilized to determine the costs of activities. Health Canada developed a Costing Companion Document for the Fee Proposal for Drugs and Medical Devices. This document outlined the costing analysis, methodology, data and costing calculations.

In calculating revised fees, Health Canada used the Treasury Board of Canada Secretariat's Guidelines on Costing and costs were based on 2014-2017 data. Data was collected via a time tracking system that gathers the level of effort for each activity, including time spent reviewing submissions and applications. Health Canada has a rigorous Time Tracking System to determine the level of effort for each submission or application as well as the costs for indirect activities. Fees were set based on the cost of delivering the current regulatory program.

Health Canada remains committed to transparency and accountability and will share costing information with stakeholders annually.

ANNUAL FEE ADJUSTMENT

Fee Proposal	Stakeholder Views	Final Fees
Annual fee adjustment tied to Consumer Price Index (CPI) of previous year	The process for how and when stakeholders will be notified of the adjustment is unclear Would like Health Canada to provide its stakeholders with sufficient notice of annual fee adjustment	Annual fee adjustment tied to CPI of previous year, published in the fall with implementation April 1st

Fees will be adjusted annually using the CPI. This approach aligns with the *Service Fees Act*. This is a change from the current 2% annual adjustment. Generally, stakeholders expressed their preference for a static annual adjustment rather than the CPI so that fees could be predictable, which would benefit their budgeting practices.

Fees will be adjusted annually on April 1st beginning on April 1, 2021 by the percentage change over 12 months in the April All-items CPI for Canada, as published by Statistics Canada under the *Statistics Act*, for the previous fiscal year and rounded up to the nearest dollar. These adjusted fee amounts will be published every fall, to provide stakeholders with sufficient notice.

SMALL BUSINESS STRATEGY

Fee Proposal	Stakeholder Views	Final Fees
Apply the Treasury Board Secretariat's small business definition[1]: "Any business, including its affiliates, that has fewer than 100 employees or between $30,000 and $5 million in annual gross revenues." New companies meeting the definition will be eligible to receive their first Pre-market submission free if the fee is greater than $10,000, one time only	The proposed small business strategy would only benefit new small businesses Lack of mitigation for the Right to Sell fee Concerned with the removal of existing mitigation for Medical Device Establishment Licensing fee which would have a negative impact on small business, even with the revised lower fee	Applying the Treasury Board Secretariat's small business definition (and the *Competition Act*'s definition of affiliates): • First Pre-market submission free regardless of fee amount • 50% mitigation for all subsequent Pre-market Evaluation fees • 25% mitigation for all Right to Sell fees • 25% mitigation for all Establishment Licence fees

Health Canada recognized that its current mitigation measures did not directly benefit small business and that many large companies were inappropriately benefiting from these measures. To rectify this situation, in the Fee Proposal, Health Canada proposed to use the Treasury Board Secretariat's definition of a small business to determine the eligibility of a company requesting small business assistance: *"Any business, including its affiliates, that has fewer than 100 employees or between $30,000 and $5 million in annual gross revenues".* Further to meeting the definition, companies would be required to provide Health Canada with a breakdown of the number of persons employed for the past 12 months; and the company's overall revenue; this information would have to be provided for the company as well as all affiliates. Once a company qualified for small business assistance, their first pre-market product submission would be free if the fee was greater than $10,000 – one time only.

Although stakeholders welcomed the position on small business, they remained concerned that Health Canada was only focusing on small business and by eliminating existing mitigation provisions it would negatively impact products with low volume sales that service niche markets. Furthermore, many stakeholders were concerned that the small business mitigation only applied to the pre-market evaluation submissions and would benefit new small businesses only.

[1] Treasury Board Secretariat, Hardwiring Sensitivity to Small Business Impacts of Regulation: Guide for the Small Business Lens, February 2012.

In response, Health Canada revised its small business strategy to provide mitigation for both pre- and post-market activities to companies that meet the Treasury Board Secretariat definition:

- First pre-market submission or application reviewed for free for new small businesses that have never previously filed with Health Canada
- A 50% reduction in all fees for subsequent pre-market submission or applications
- A 25% reduction of all right to sell fees and Establishment Licence fees

Health Canada will adopt the definition for affiliation[2] from the *Competition Act*, and companies that apply for small business assistance that are affiliated must meet this definition as well.

Health Canada remains confident that its small business strategy will minimize the impact of fees for small businesses and promote growth and innovation.

MITIGATION MEASURES

Fee Proposal	Stakeholder Views	Final Fees
Waive first Pre-market drug submission fee for a drug on the *List of Drugs for an Urgent Public Health Need*, as per the *Access to Drugs in Exceptional Circumstances Regulations* Elimination of fee deferrals and mitigation based on product sales	Would like Health Canada to maintain its mitigation measures, especially for Establishment Licensing fees and Right to Sell fees Would like Health Canada to incorporate mitigation for public health institutions producing radiopharmaceuticals	Waive first Pre-market drug submission fee for a drug on the *List of Drugs for an Urgent Public Health Need*, as per the *Access to Drugs in Exceptional Circumstances Regulations* Elimination of fee deferrals and mitigation based on product sales All fees waived for publicly funded health care institutions Drug Establishment Licence fees pro-rated quarterly for a new application

In the Fee Proposal, Health Canada proposed to eliminate the current mitigation provisions based on product sales as well as fee deferrals. Stakeholders, especially in the Medical Devices, Generic Drugs,

[2]Affiliation: a) one entity is affiliated with another entity if one of them is the subsidiary of the other or both are subsidiaries of the same entity or each of them is controlled by the same entity or individual; b) if two entities are affiliated with the same at the same time, they are deemed to be affiliated with the other; and c) an individual is affiliated with an entity if the individual controls the entity.

Radiopharmaceutical Drugs and Veterinary Drugs sectors were concerned with the impact of eliminating the current mitigation measures and the limited new mitigation. Stakeholders reiterated throughout the consultations that eliminating the existing mitigation provisions would have a negative impact for products with low volume sales that service niche markets. In addition, some stakeholders voiced their concerns with paying a full Establishment Licence fee despite not having their new licence for a full year.

Health Canada expanded its mitigation to include an exemption for publicly funded health care institutions to address the concerns of the Radiopharmaceutical industry and pro-rated new or amended Drug Establishment Licence fees for a new application. In addition, Health Canada will waive the first Pre-market drug submission fee for a drug on the *List of Drugs for an Urgent Public Health Need*, as per the *Access to Drugs in Exceptional Circumstances Regulations*. Effective April 1, 2020, mitigation will include a full remission for the first pre-market drug submission / application for a product (or one with the same medicinal ingredient, route of administration and indication and a comparable dosage form) on the *List of Drugs for an Urgent Public Health Need*.

PERFORMANCE STANDARDS AND REPORTING

Fee Proposal	**Stakeholder Views**	**Final Fees**
All existing standards will remain unchanged, except for: • Human Drug Evaluation fee categories Labelling Only (120 days) and DINA Labelling Standard (60 days) • Human Drug and Veterinary Drug Right to Sell fees (20 days) • Disinfectant - Labelling Only (120 days) All new fee categories have a performance standard	Performance standards should be updated as fees are updated Performance standard for Labelling Only fees is too long Medical Device performance standard does not include screening time to approval Concerned with the 250 day performance standard for Drug Establishment Licence	All existing standards will remain unchanged, except for: • Human Drug Evaluation fee categories Labelling Only (120 days) and DINA Labelling Standard (60 days) • Human Drug and Veterinary Drug Right to Sell fees (20 days) • Disinfectant - Labelling Only (90 days) All new fee categories have a performance standard
Provide quarterly and annual performance reports upon request	Would like Health Canada to review its performance annually to create program efficiencies, and to meet with	Provide quarterly and annual performance reports upon request

	industry annually to discuss its performance	Annual meeting with industry to discuss performance, efficiencies and other areas of interest

In the Fee Proposal, Health Canada proposed maintaining its standards with a few exceptions while continuing to publish its performance annually. Overall, stakeholders had minor concerns with this approach; however, they would like Health Canada to increase its program efficiency and effectiveness by modernizing its approaches and improving performance standards. Stakeholders from the Disinfectant Sector had concerns with some of the standards for their submissions / applications. The Non-prescription (Over the Counter) and Veterinary Drugs sectors noted that Drug Establishment Licence fees have overly long performance standards. Stakeholders from the medical device sector would like performance standards to include screening time to approval.

In response, Health Canada amended its Human Drug Evaluation performance standard for Disinfectant Labelling Only from 120 to 90 days. Health Canada recognizes that time to approval is an important metric for industry and for Canadians, but, the standards to be used to measure accountability and potentially trigger financial penalties will remain for the review of product submissions for pre-market evaluation. However, Health Canada remains committed to improving its service delivery. This includes automating and streamlining its processes, aligning with health technology assessors to facilitate timely access to new products, updating Guidance Documents and assisting with filing submissions / applications when necessary. Health Canada will also engage with stakeholders annually to discuss performance, costs and efficiencies.

Performance Reporting

Accountability is a key component to the valuable relationship Health Canada has with its stakeholders. Currently, Health Canada provides quarterly and annual performance reports upon request. Stakeholders would like Health Canada to review its performance annually by creating program efficiencies as they believe this will strengthen the accountability and delivery of the regulatory program.

In addition to continuing to provide quarterly and annual reports upon request, Health Canada will also meet annually with stakeholders to discuss performance efficiencies and other areas of improvement to enhance the regulatory program.

PENALTY PROVISION

Fee Proposal	Stakeholder Views	Final Fees
An individual submission that exceeds the performance standard will receive a rebate of 25%; and a '*Pause the Clock*' provision to limit the standard to the time spent by Health Canada on that submission	Overall, stakeholders agreed the new penalty provision is appropriate; some suggested a sliding scale to ensure ongoing accountability Would like Health Canada to consult with stakeholders on the '*Pause the Clock*' provision	An individual submission or application that exceeds the performance standard will receive a rebate of 25% Penalties will not apply to joint and parallel review submissions or medical device combination applications Consultations on the '*Pause the Clock*' provisions concluded and the final guidance will be implemented April 1, 2020

Health Canada remains committed to providing timely, efficient and effective services. The Department proposed to increase its accountability by introducing a 25% rebate for all applications that miss the standard. Overall, stakeholders were supportive and agreed with this approach, however, some stakeholders recommended a sliding scale whereby penalties would escalate when a performance standard is missed by a growing amount. Stakeholders noted this would ensure that reviews are concluded as expeditiously as possible even if the standard is missed.

Given the general support of the proposed penalty model, Health Canada will maintain the proposed penalty provision and will rebate the sponsor 25% of the associated fee for missed performance. Health Canada recognizes that accountability continues even after a standard is missed and will continue to report metrics to ensure transparency and accountability of submission standards. To complement this penalty model, a '*Pause the Clock*' model will be implemented. The pause the clock is a mechanism that allows for the review clock to be formally paused, under specified circumstances or points in time. This mechanism is not unique to Canada as many other international regulators also possess similar processes. Pause the Clock will allow for flexibility to accommodate certain defined circumstances, such as a request from a sponsor for additional time to respond to a clarification request, and as such, Health Canada is only accountable for the time it spends on a particular submission/application. Health Canada consulted with stakeholders on potential triggers to ensure that only Health Canada review time is included in reporting against the performance standards and final policies will be in place by April 1, 2020.

Missed performance standards for joint review and parallel review submissions with other international regulatory agencies will not trigger penalties. In addition, medical device combination applications[3] will be exempt from penalties.

TIMING OF PAYMENT

Fee Proposal	Stakeholder Views	Final Fees
Full Pre-market fees collected upfront	A few stakeholders, specifically small businesses, were concerned paying the full fee upfront would put pressure on their budgets	Full pre-market fees collected upfront

Currently, Health Canada invoices for 75% of the pre-market fee before reviewing the submission / application, and the outstanding 25% following the approval or rejection of a product. In the Fee Proposal, Health Canada proposed amending this to invoice for the full fee at the time of submission / application to create efficiencies in the billing process. A few stakeholders voiced their concerns with the proposed approach; noting that this would have a negative effect on their budgets. Health Canada will proceed with its proposed approach. In its current system, the majority of fees are collected before the review of a drug submission. Adjusting the timing of payment will simplify the billing process and align with the practices of other international regulators.

SPECIFIC FEE LINE CHANGES

Some stakeholders had comments on specific parts of the fee proposal, which are summarized below.

MEDICAL DEVICE FEES

In the Fee Proposal, Health Canada proposed specific changes to the medical device pre-market evaluation fees. These changes included: merging all Class IV device applications into a single fee category and starting to charge for applications currently reviewed without a fees such as the Class II amendments and Private Label applications. Stakeholders were concerned with these changes and presented counter proposals, including new fees for administrative submissions.

[3] Medical device combination products contain both a medical device and a drug component but the principal mechanism of action of the product is achieved through the medical device component.

Health Canada proposed and will implement a significantly reduced Medical Device Establishment Licence fee, based on updated costs and due to the fee setting ratio for the Right to Sell fees, the medical device Right to Sell fee will now be reduced to less than the current fee.

Moving forward, Health Canada will continue to engage with stakeholders annually, and future suggestions will be considered when the fees are next reviewed.

HUMAN DRUG FEES

While the fee structure for pre-market evaluation fees remains relatively unchanged from current fees, Health Canada proposed some adjustments to fee categories, including eliminating certain categories (Published Data Only and Rx Switch submissions which will now be processed under other categories such a Clinical Data), introducing new categories (Safety, Labelling Only generic/disinfectant submissions) and clarifying definitions and how submissions would be categorized. These changes were made to better align with the requirements and obligations imposed by recent amendments to the *Food and Drugs Act* and Plain Language Labelling regulatory amendments.

Some stakeholders raised concerns with new fee categories, or the elimination of some fee categories. Others challenged the appropriateness of a fee structure that charges for overlapping submissions, as is often the case for biosimilar submissions.

Beyond the magnitude of the fee increases and the costing methodology, there were not a high number of issues raised regarding the Drug Establishment Licence fees. Starting April 1, 2020, the Drug Establishment Licence fee will be simplified by charging one fee for each building's most intensive activity from a regulatory oversight point of view. All sites managing Active Pharmaceutical Ingredients will now be charged fees, all Drug Establishment Licence with foreign sites will pay a fee for each foreign site listed on the licence, and any amendment to add a building to a licence will be charged a fee. In addition, all new applications and amendments to add a new building will be pro-rated quarterly based on when in the Government of Canada fiscal year the application is made.

For the Drug Right to Sell fee, stakeholders wanted clarification as to whether the fee would apply to dormant drugs. In addition, they raised concerns about the cumulative impact the revised fee will have on companies with large product portfolios as they feel it will have a significant negative financial effect and possibly reduce access to products as a result of increases in drug discontinuation and shortages. Fees for dormant drugs will not be charged provided the company has notified Health Canada as per the regulatory requirements.

VETERINARY DRUG FEES

The fees for veterinary products were the most significantly impacted overall by the proposal. Other than the CPI adjustment made on April 1, 2019, the veterinary fees have not been changed since they

were originally implemented in stages between 1995-1998. In addition, a new fee for Veterinary Health Product Notification was implemented, as per recent regulations introducing that regulatory program, and the Veterinary only Drug Establishment Licensing fees were initially placed on par with fees for establishments dealing with human drugs. Other recent regulatory changes (including charging fees for foreign sites dealing with Active Pharmaceutical Ingredients and charging fees for veterinarians and pharmacists who import medically important antimicrobial for use in animals) also expanded the scope of who is required to pay fees.

Stakeholders voiced strong concerns regarding the impact of these sudden increases in fees, citing market shares and small margins due to low product sales, especially for Minor Use and Minor Species (MUMS) that could not support the new business model. In response, Health Canada will be phasing in pre-market and Veterinary only Drug Establishment Licence fees for companies over seven years and has reduced the fee-setting ratio for the veterinary drug pre-market evaluation fees to 50%. To provide stakeholders with time to adjust to the revised fees, the Veterinary only Drug Establishment Licence fee will start its phase in from the current average fee paid by veterinary drug only establishments, rather than being set at the current average fee paid by human drug establishments.

Recognizing that the veterinary drug pre-market evaluation fees are not structured in an effective manner, Health Canada will be engaging with the veterinary sector starting in 2019 to revamp the fee structure to better reflect current regulatory pathways. This will also be an opportunity to address concerns regarding fees for MUMS products.

CONCLUSION AND NEXT STEPS

Health Canada has been working diligently to strengthen its regulatory program. A key component to this is its cost recovery regime. Health Canada has been actively engaging with its stakeholders and the Final Fees outlined above were developed with their feedback. Following the publication of the Fee Proposal in October 2017, significant changes were made as a result of issues raised by stakeholders. Following the Feedback Process on the Revised Fee Proposal in May 2018, additional changes to the Veterinary only Drug Establishment Licence fees were made. These key stakeholder opportunities ensure that Health Canada makes appropriate changes to its regulatory program.

Moving forward, Health Canada will be meeting annually with stakeholders to discuss key elements of cost recovery including performance, costs and program efficiencies.

A Ministerial Order detailing the new fees as well as the repeal of the existing fees will be published May 29, 2019 in *Canada Gazette*, Part II. These new fees and remissions will come into force on April 1, 2020. All impacted guidance documents, forms and web pages will be updated accordingly.

ANNEX A: FEES AND PERFORMANCE STANDARDS FOR DRUGS AND MEDICAL DEVICES (2020 ONWARD)

Note: all fees for 2021-2022 and beyond will be adjusted by a cumulative CPI amount; the actual fees payable will be different than those published in these tables, depending on the actual CPI rates in the coming years.

Fees for Examination of a Submission – Drugs for Human Use

Item	Submission Class	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Performance Standard
1	New active substance	Submissions in support of a drug, other than a disinfectant, that contains a medicinal ingredient not previously approved in a drug for sale in Canada and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph	$400,288	$437,884	$475,481	$513,077	300 calendar days to complete Review 1*
2	Clinical or nonclinical data and chemistry and manufacturing data	Submissions based on clinical or nonclinical data and chemistry and manufacturing data for a drug that does not include a new active substance	$204,197	$224,691	$245,185	$265,678	For drugs under Division 1 of the *Food and Drug Regulations*: 210 calendar days to complete Review 1* For drugs under Division 8 of the *Food and Drug Regulations*: 300 calendar days to complete Review 1*
3	Clinical or nonclinical data only	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance	$90,864	$95,987	$101,110	$106,232	For drugs under Division 1 of the *Food and Drug Regulations*: 210 calendar days to complete Review 1* For drugs under Division 8 of *Food and Drug Regulations*: 300

Item	Submission Class	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Performance Standard
							calendar days to complete Review 1*
4	Comparative studies	Submissions based on comparative studies (e.g., clinical or non-clinical data, bioavailability data and data on the pharmacokinetics and pharmacodynamics of the drug) with or without chemistry and manufacturing data for a drug that does not include a new active substance	$53,836	$55,848	$57,859	$59,870	For drugs under Division 1 of the *Food and Drug Regulations*: 210 calendar days to complete Review 1* For drugs under Division 8 of *Food and Drug Regulations*: 180 calendar days to complete Review 1*
5	Chemistry and manufacturing data only	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance	$27,587	$30,670	$33,752	$36,835	For drugs under Division 1 of the *Food and Drug Regulations*: 210 calendar days to complete Review 1* For drugs under Division 8 of *Food and Drug Regulations*: 180 calendar days to complete Review 1*
6	Clinical or nonclinical data only, in support of safety updates to the labelling	Submissions based only on clinical or non-clinical data, in support of safety updates to the labelling materials for a new drug that does not include a new active substance	$19,442	$19,442	$19,442	$19,442	120 calendar days to complete Review 1*
7	Labelling only	Submissions, other than those described in item 8, 11 or 12, of labelling material, that include data in support of the following: brand name assessment, standardized or published test methods, in vitro or in vivo photostability	$3,816	$4,328	$4,841	$5,353	120 calendar days to complete Review 1*

Item	Submission Class	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Performance Standard
		or applications for a drug identification number in support of changes to brand names of non-prescription drugs (but not including examination of other supporting clinical or non-clinical data, comparative data, or chemistry and manufacturing data)					
8	Labelling only (generic drugs)	Submissions in support of a change to the labelling to be consistent with the Canadian reference product that do not include any additional labelling updates requiring a labelling assessment	$2,010	$2,010	$2,010	$2,010	120 calendar days to complete Review 1*
9	Administrative submission	Submissions in support of a change in the manufacturer's name or brand name, including the following: changes in ownership of the drug, request for an additional brand name or changes resulting from a licensing agreement being entered into by two manufacturers that do not require an assessment of labelling material or brand name (e.g., post-authorization label changes filed by licensees to remain identical to licensor's drug and post-authorization chemistry and manufacturing updates for drugs listed in Schedule C or D of the *Food and Drugs Act*)	$432	$540	$676	$845	45 calendar days to review

Item	Submission Class	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Performance Standard
10	Disinfectant – full review	Submissions, other than those described in item 11, that include data in support of a disinfectant	$5,712	$7,140	$8,925	$11,157	For drugs under Division 1 of the *Food and Drug Regulations*: 180** or 210 calendar days to complete Review 1* For drugs under Division 8 of *Food and Drug Regulations*: 300 calendar days to complete Review 1*
11	Labelling only (disinfectants)	Submissions in support of changes to the labelling of disinfectants that do not require supporting data, submissions in support of safety updates for disinfectants that are new drugs or submissions in support of a change in the manufacturer's name or brand name that requires a review of labelling material due to deviations from the previously authorized labelling or drug	$2,507	$2,507	$2,507	$2,507	90 calendar days to complete Review 1*
12	Drug identification number application — labelling standards	Applications, including those that pertain to changes to brand names for non-prescription drugs, that include an attestation of compliance with a labelling standard or Category IV Monograph for a drug and that do not include clinical or non-clinical data or chemistry and manufacturing data	$1,616	$1,616	$1,616	$1,616	60 calendar days to complete Review 1*

*Review 1 is the period from the date of acceptance to the date of the first decision (Notice of Deficiency, Notice of Non-compliance, Notice of Compliance with Conditions or Notice of Compliance).
**The 180 calendar days to complete Review 1 is a Label Only assessment that does not include the submission of data. It relies on bridged / cross-referenced data from other submissions.

Fees for Examination of a Submission – Drugs for Veterinary Use Only

Item	Component	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	Application for drug identification number								
1	Information, other than that referred to in item 2, to support an application for a drug identification number, including the submission of labelling material for a second review, if required	$918	$1,148	$1,436	$1,714	$1,959	$2,204	$2,448	120 calendar days to complete Review 1*
2	Published references or other data	$638	$798	$998	$1,191	$1,361	$1,532	$1,701	
3	Documentation to support a change of manufacturer, a change to the name of a manufacturer or a change to the brand name of a drug	$320	$400	$500	$596	$681	$765	$850	
	Notification — veterinary health product								
4	Information contained in a notification filed under subsection C.01.615(1) of the *Food and Drug Regulations* in respect of a veterinary health product	$486	$486	$486	$486	$486	$486	$486	30 calendar days to process notification
	New drug submission								
5	Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in one animal species (in the case of an antiparasitic drug,	$20,375	$25,469	$31,837	$38,033	$43,467	$48,900	$54,333	300 calendar days to process notification

Item	Component	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	several indications in one food animal species)								
6	Efficacy and safety data (in the intended species) to support a single route of administration and dosage form for an antiparasitic drug in one non-food animal species	$12,342	$15,428	$19,286	$23,039	$26,331	$29,622	$32,913	
7	Efficacy and safety data (in the intended species) to support a single route of administration, dosage form and indication in two animal species, or a single route of administration and dosage form and two indications in one animal species	$29,631	$37,040	$46,300	$55,312	$63,214	$71,116	$79,017	
8	Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	$40,125	$50,157	$62,697	$74,899	$85,599	$96,299	$106,998	
9	Comparative (pharmacodynamic, clinical or bioavailability) data to support an additional route of administration	$3,698	$4,623	$5,779	$6,903	$7,889	$8,876	$9,861	
10	Comparative (pharmacodynamic, clinical or bioavailability) data to support each additional strength	$612	$765	$957	$1,143	$1,306	$1,469	$1,632	
11	For food-producing animals, toxicity, metabolism and residue depletion	$27,783	$34,729	$43,412	$51,861	$59,270	$66,678	$74,086	

Item	Component	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	studies to establish an acceptable daily intake with a safety factor of 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species								
12	For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of less than 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	$37,040	$46,300	$57,875	$69,140	$79,017	$88,893	$98,770	
13	For food-producing animals, residue depletion studies to establish a withdrawal period for an additional dosage form, dosage or route of administration	$3,698	$4,623	$5,779	$6,903	$7,889	$8,876	$9,861	
14	For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism and residue depletion studies to establish a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of	$18,513	$23,142	$28,928	$34,558	$39,495	$44,432	$49,368	

Item	Component	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	administration in an additional species								
15	Chemistry and manufacturing data for a non compendial medicinal ingredient of a drug	$6,171	$7,715	$9,644	$11,520	$13,166	$14,811	$16,456	
16	Chemistry and manufacturing data to support one strength of a single dosage form	$6,171	$7,715	$9,644	$11,520	$13,166	$14,811	$16,456	
17	Chemistry and manufacturing data to support an additional strength of a single dosage form submitted at the same time as item 16	$3,086	$3,858	$4,823	$5,760	$6,584	$7,407	$8,229	
18	Documentation to support a change of manufacturer	$320	$400	$500	$596	$681	$765	$850	
	Supplement to a new drug submission								
19	Efficacy data to support an additional indication in one animal species	$16,053	$20,067	$25,084	$29,965	$34,246	$38,527	$42,807	240 calendar days to complete Review 1*
20	Efficacy and safety data (in the intended species) to support a single route of administration and dosage form for an antiparasitic drug in one non-food animal species	$12,342	$15,428	$19,286	$23,039	$26,331	$29,622	$32,913	
21	Efficacy and safety data (in the intended species) to support an indication in another animal species	$20,375	$25,469	$31,837	$38,033	$43,467	$48,900	$54,333	
22	Efficacy and safety data (in the intended species) to support a single	$29,631	$37,040	$46,300	$55,312	$63,214	$71,116	$79,017	

Item	Component	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	route of administration, dosage form and indication in two animal species, or a single route of administration and dosage form and two indications in one animal species								
23	Efficacy and safety data (in the intended species) to support a growth promotion or production enhancement indication in one animal species	$40,125	$50,157	$62,697	$74,899	$85,599	$96,299	$106,998	
24	Efficacy and safety data (in the intended species) to support the concurrent use of two drugs approved for the same animal species	$9,869	$12,336	$15,421	$18,422	$21,053	$23,685	$26,316	
25	Comparative (pharmacodynamic, clinical or bioavailability) data to support an additional route of administration	$3,698	$4,623	$5,779	$6,903	$7,889	$8,876	$9,861	
26	Comparative (pharmacodynamic, clinical or bioavailability) data to support each additional strength	$612	$765	$957	$1,143	$1,306	$1,469	$1,632	
27	For food-producing animals, residue depletion studies to establish a new withdrawal period for a change in the dosage or route of administration of an approved dosage form in one species	$3,698	$4,623	$5,779	$6,903	$7,889	$8,876	$9,861	
28	For food-producing animals,	$18,513	$23,142	$28,928	$34,558	$39,495	$44,432	$49,368	

Item	Component	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	metabolism and residue depletion studies to establish a maximum residue limit and a withdrawal period for a single dosage and route of administration of an approved dosage form in an additional species								
29	For food-producing animals, toxicity studies to support a change of an established acceptable daily intake, a maximum residue limit and a withdrawal period	$9,257	$11,571	$14,464	$17,279	$19,748	$22,216	$24,684	
30	For the concurrent use of two drugs in a species of food-producing animals, residue depletion studies to determine if an extension to existing withdrawal periods is required	$7,409	$9,261	$11,576	$13,829	$15,804	$17,780	$19,755	
31	Chemistry and manufacturing data to support a change in the source of a medicinal ingredient or its manufacturing process	$6,171	$7,715	$9,644	$11,520	$13,166	$14,811	$16,456	
32	Chemistry and manufacturing data to support a change in formulation or dosage form	$3,086	$3,858	$4,823	$5,760	$6,584	$7,407	$8,229	
33	Chemistry and manufacturing data to support a change in the packaging or sterilization process	$2,462	$3,078	$3,848	$4,595	$5,250	$5,906	$6,562	
34	Chemistry and manufacturing data	$1,850	$2,313	$2,891	$3,452	$3,945	$4,437	$4,930	

Item	Component	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	to support an extension of the expiry date								
35	Chemistry and manufacturing data to support the concurrent use of two drugs	$1,850	$2,313	$2,891	$3,452	$3,945	$4,437	$4,930	
36	Chemistry and manufacturing data to support a change in the manufacturing site for parenteral dosage form	$612	$765	$957	$1,143	$1,306	$1,469	$1,632	
37	Documentation to support a change to the brand name of a drug	$320	$400	$500	$596	$681	$765	$850	
	Abbreviated new drug submission or supplement to an abbreviated new drug submission								
38	Comparative (pharmacodynamic, clinical or bioavailability) data to support a single route of administration and dosage form	$3,698	$4,623	$5,779	$6,903	$7,889	$8,876	$9,861	Abbreviated new drug submission: 300 calendar days to complete Review 1*
39	For food-producing animals, residue depletion studies to confirm that the withdrawal periods for each species fall within the conditions of use for the Canadian reference product	$3,698	$4,623	$5,779	$6,903	$7,889	$8,876	$9,861	Supplement to an abbreviated new drug submission: 240 calendar days to complete Review 1*
40	Chemistry and manufacturing data for a non compendial medicinal ingredient of a drug	$6,171	$7,715	$9,644	$11,520	$13,166	$14,811	$16,456	
41	Chemistry and manufacturing data to support a single dosage form	$6,171	$7,715	$9,644	$11,520	$13,166	$14,811	$16,456	
42	Documentation to support **(a)** a change of manufacturer, in the case of an	$320	$400	$500	$596	$681	$765	$850	

Item	Component	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	abbreviated new drug submission; or **(b)** a change to the brand name of a drug, in the case of a supplement to an abbreviated new drug submission								
	Preclinical submission								
43	Efficacy and safety data (in the intended species) and protocol to support the conduct of clinical studies relative to a single dosage form, route of administration and indication in one species	$6,171	$7,715	$9,644	$11,520	$13,166	$14,811	$16,456	60 calendar days to review application
44	Efficacy data and protocol to support the conduct of clinical studies relative to a single route of administration and indication with a dosage form for which a notice of compliance has been issued for use in the species to be treated	$4,935	$6,169	$7,712	$9,211	$10,527	$11,843	$13,158	
45	For food-producing animals, toxicity, metabolism and residue depletion studies to establish a temporary acceptable daily intake, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	$18,513	$23,142	$28,928	$34,558	$39,495	$44,432	$49,368	
46	For food-producing animals, toxicity,	$27,783	$34,729	$43,412	$51,861	$59,270	$66,678	$74,086	

Item	Component	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species								
47	For food-producing animals, toxicity, metabolism and residue depletion studies to establish an acceptable daily intake with a safety factor of less than 1,000, a maximum residue limit and a withdrawal period for a single dosage form, dosage and route of administration in one species	$37,040	$46,300	$57,875	$69,140	$79,017	$88,893	$98,770	
48	For food-producing animals (once an acceptable daily intake with a safety factor of 1,000 or less has been established), metabolism studies to establish a withdrawal period for a single dosage form, dosage and route of administration in an additional species	$9,257	$11,571	$14,464	$17,279	$19,748	$22,216	$24,684	
49	Chemistry and manufacturing data to support a single dosage form containing a non compendial	$6,171	$7,715	$9,644	$11,520	$13,166	$14,811	$16,456	

Item	Component	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	medicinal ingredient								
50	Chemistry and manufacturing data to support a single dosage form containing a compendial medicinal ingredient	$3,086	$3,858	$4,823	$5,760	$6,584	$7,407	$8,229	
	Sale of a new drug for emergency treatment								
51	Information and material to support the sale of a new drug to be used in the emergency treatment of a non-food-producing animal	$51	$51	$51	$51	$51	$51	$51	2 business days to review application
52	Information and material to support the sale of a new drug to be used in the emergency treatment of a food producing animal	$102	$102	$102	$102	$102	$102	$102	
	Experimental studies certificate								
53	Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a non-food producing animal	$980	$980	$980	$980	$980	$980	$980	60 calendar days to review application
54	Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that of a previously authorized experimental studies certificate for a drug to be administered to a non-food producing animal	$490	$490	$490	$490	$490	$490	$490	
55	Information and material to support	$2,958	$2,958	$2,958	$2,958	$2,958	$2,958	$2,958	

Item	Component	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	the issuance of an experimental studies certificate for a drug to be administered to a food-producing animal								
56	Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that of a previously authorized experimental studies certificate for a drug to be administered to a food-producing animal	$490	$490	$490	$490	$490	$490	$490	
	Notifiable change								
57	Information and material to support an application for a notifiable change	$1,658	$2,073	$2,591	$3,095	$3,537	$3,978	$4,420	90 calendar days to review application
	Protocol								
58	A protocol that is filed with the Minister and may support a new drug submission, an abbreviated new drug submission, a supplement to a new drug submission or abbreviated new drug submission, a preclinical submission or information and material that is filed for the purpose of obtaining an experimental studies certificate	$1,658	$2,073	$2,591	$3,095	$3,537	$3,978	$4,420	90 calendar days to review package

*Review 1 is the period from the date of acceptance to the date of the first decision (Notice of Deficiency, Notice of Non-compliance, Notice of Compliance with Conditions or Notice of Compliance).

*** While there are individual fees for each component and a submission / application can be made up of more than one component, the submission / application is reviewed as one package.

Fees for Examination of an Application for an Establishment Licence – Drugs for Human Use

Item	Name of Fee	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Performance Standard
	Drug Establishment Licence	Application for new licence, annual review of licence, or amendment to a licence to add a new building in Canada					250 calendar days to issue decision
	Activity						
1	Fabrication — sterile dosage form		$41,626	$41,730	$41,834	$41,937	
2	Importation		$27,359	$29,033	$30,707	$32,380	
3	Fabrication — nonsterile dosage form		$27,000	$28,364	$29,727	$31,091	
4	Distribution		$12,560	$13,882	$15,205	$16,527	
5	Wholesaling		$4,937	$6,171	$7,715	$9,644	
6	Packaging/labelling		$6,061	$6,061	$6,061	$6,061	
7	Testing		$2,560	$3,200	$4,001	$5,002	
8	Foreign building (Each)		$918	$918	$918	$918	

Fees for Examination of an Application for an Establishment Licence – Drugs for Veterinary Use Only

Item	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
	Drug Establishment Licence								
	Application for new licence, annual review of licence, or amendment to a licence to add a new building in Canada								250 calendar days to issue decision
	Activity								
1	Fabrication — sterile dosage form	$40,198	$40,487	$40,777	$41,068	$41,357	$41,647	$41,937	

Item	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Fee Fiscal Year 2024-25	Fee Fiscal Year 2025-26	Fee Fiscal Year 2026-27	Performance Standard
2	Importation	$10,715	$13,393	$16,742	$20,927	$26,158	$32,380	$32,380	
3	Fabrication — nonsterile dosage form	$8,782	$10,978	$13,722	$17,152	$21,440	$26,800	$31,091	
4	Distribution	$4,835	$6,043	$7,555	$9,443	$11,803	$14,754	$16,527	
5	Wholesaling	$1,933	$2,416	$3,020	$3,774	$4,718	$5,898	$7,372	
6	Packaging/labelling	$6,061	$6,061	$6,061	$6,061	$6,061	$6,061	$6,061	
7	Testing	$1,315	$1,644	$2,055	$2,569	$3,210	$4,013	$5,002	
8	Foreign building (each)	$765	$918	$918	$918	$918	$918	$918	

Fees for the Right to Sell Drugs for Human Use

Item	Name of Fee	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Performance Standard
	Right to Sell Drugs for Human Use	The annual fee for the right to sell a drug (Disinfectant, Non-prescription drug, or a Drug other than one referred to earlier) for which a drug identification number has been assigned under section C.01.014.2 (1) of the *Food and Drug Regulations*					20 calendar days to update Drug Product Database following receipt of a complete Annual Notification Package
	Type of Drug						
1	Disinfectant		$1,285	$1,344	$1,403	$1,462	
2	Non-Prescription drug		$1,623	$2,022	$2,421	$2,820	
3	Drug other than one referred to in item 1 or 2		$1,836	$2,754	$4,080	$4,679	

Fees for the Right to Sell Drugs for Veterinary Use Only

Item	Name of Fee	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Performance Standard
1	Right to Sell Drugs for Veterinary Use Only	The annual fee for the right to sell a drug for veterinary use only for which a drug identification number has been assigned under section C.01.014.2 (1) of the *Food and Drug Regulations*	$312	$367	$422	$477	20 calendar days to update Drug Product Database following receipt of a complete Annual Notification Package

Fees for the Examination of an Application for a Medical Device Licence

Item	Category	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Performance Standard
1	Applications for Class II licence	Applications for Class II medical device licence other than those referred to in item 10	$450	$478	$505	$533	15 calendar days to review
2	Applications for Class II licence amendment	Applications for amendment of Class II medical device licence other than those referred to in item 10	$272	$272	$272	$272	15 calendar days to review
3	Applications for Class III licence	Applications for Class III medical device licence other than those referred to in item 4 or 10	$7,477	$8,912	$10,347	$11,783	60 calendar days to complete Review 1*
4	Applications for Class III licence (near patient)	Applications for Class III medical device licence for a near patient in vitro diagnostic device	$12,851	$16,064	$20,081	$25,102	60 calendar days to complete Review 1*
5	Applications for Class III licence amendment — changes in manufacturing	Applications for amendment of Class III medical device licence — changes in manufacturing process, facility or equipment or manufacturing quality control procedures	$1,903	$2,379	$2,974	$3,717	60 calendar days to complete Review 1*
6	Applications for Class III licence amendment	Applications for amendment of Class III medical device licence — significant	$6,608	$7,558	$8,508	$9,458	60 calendar days to complete Review 1*

Item	Category	Description	Fee Fiscal Year 2020-21	Fee Fiscal Year 2021-22	Fee Fiscal Year 2022-23	Fee Fiscal Year 2023-24	Performance Standard
	— significant changes not related to manufacturing	changes other than those referred to in item 5					
7	Applications for Class IV licence	Applications for Class IV medical device licence other than those referred to in item 10	$24,345	$24,748	$25,151	$25,554	75 calendar days to complete Review 1*
8	Applications for Class IV licence amendment — changes in manufacturing	Applications for amendment of Class IV medical device licence — changes referred to in paragraph 34(a) of the *Medical Devices Regulations* that relate to manufacturing	$1,903	$2,379	$2,974	$3,717	75 calendar days to complete Review 1*
9	Applications for Class IV licence amendment — significant changes not related to manufacturing	Applications for amendment of Class IV medical device licence— any other changes referred to in paragraph 34(a) or (b) of the *Medical Devices Regulations*	$8,057	$9,983	$11,752	$13,521	75 calendar days to complete Review 1*
10	Applications for Class II, III or Class IV licence or licence amendment — private label medical device	Applications for Class II, III or IV medical device licence or applications for amendment of such a licence — private label medical device	$147	$147	$147	$147	15 calendar days to review

*Review 1 is the period from the date of acceptance of an administratively complete application to the date of the first decision (for Class II and Private Label Applications: Licence, Screening Deficiency Letter, Rejection Letter, Withdrawal; for Class III and IV: Licence, Additional Information Request, Refusal Letter, or Withdrawal).

Fees for Examination of an Application for an Establishment Licence – Medical Devices

Item	Name of Fee	Description	Fee Fiscal Year 2020-21	Performance Standard
1	Medical Device Establishment Licence	Applications for new licence and annual review of licence	$4,590	120 calendar days to issue decision

Fees for the Right to Sell Licensed Class II, III or IV Medical Devices

Item	Name of Fee	Description	Fee Fiscal Year 2020-21	Performance Standard
1	Right to Sell Medical Device	The annual fee for the right to sell a licensed Class II, III or IV medical device	$381	20 days to update Medical Device Licence Listing database following receipt of a complete Annual Notification Package