Health Canada Santé Canada

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FEE PROPOSAL FOR DRUGS AND MEDICAL DEVICES (for consultation)

October 2017

Canada

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SECTION I: WHY IS HEALTH CANADA UPDATING ITS FEES?

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. One of the roles the department plays in carrying out this mandate is that of a regulator of drugs and medical devices through the scientific evaluation of products before they are authorized for sale, the monitoring of these products once made available to Canadians, and verifying compliance and acting on non-compliance using tools such as inspections. Fees are charged to industry in relation to these regulatory activities.

Health Canada last updated its fees for human drugs and medical devices in 2011 based on 2007 costing data. Fees for veterinary drugs were set in stages between the years of 1995-1998 and have not been updated since then. The fees, as they stand now, do not reflect the current costs of the department.

THE GOVERNMENT OF CANADA HAS CHANGED ITS APPROACH TO FEES

Budget 2017 signalled the Government of Canada's commitment to modernize business fees, stating that "businesses should pay their fair share for the services the Government provides". Reflecting this commitment, the 2017 *Budget Implementation Act* replaced the *User Fees Act* with the *Service Fees Act*.

In addition, Budget 2017 provided authorities to the Minister of Health to set fees under the *Food and Drugs Act* via Ministerial Order and granted an exemption from the *Services Fees Act*. As a result of these new authorities, Health Canada will have the flexibility to set and adjust its fees in a timely way so that they better reflect actual costs and allow the department to more effectively deliver its regulatory programs. Health Canada is committed to maintaining a strong accountability regime by continuing to report annually, reviewing international comparisons when establishing or revising fees, continued engagement with stakeholders and appropriate performance standards.

CHANGE OF ENVIRONMENT

The globalization of pharmaceutical and medical device industries means that many drugs and medical devices follow complex pathways through multi-step supply chains prior to reaching Canada. There are increasing expectations for Health Canada to rigorously monitor the safety, quality and effectiveness of products made available to Canadians and the health care system. These global realities have fundamentally changed the environment for regulating these products, increased the complexity of regulatory work, and created new regulatory challenges for Health Canada.

The department is faced with an increased volume of work as well as added complexity from globalization, technological advancement and more sophisticated data and systems. These factors have increased the costs of doing business, and placed pressure on the ability of the department to deliver services with existing resources. While Health Canada has remained internationally competitive in meeting performance standards, taxpayers are assuming an increasing economic burden because of outdated fees charged to industry.

PREDICTABILITY FOR INDUSTRY

Health Canada understands the importance of predictability in regulatory program delivery and will maintain measures to fulfill this objective. The department will continue to be agile and responsive to the needs of both Canadians and industry, by meeting performance standards and through continued transparency and strong regulatory program delivery.

SECTION II: WHAT WILL BE IMPACTED?

This fee proposal applies to regulatory activities related to human drugs, veterinary drugs and medical devices, for the following three fee lines:

Submission / Application Evaluation (EVAL) fees	Establishment Licensing (EL) fees	Right-to-Sell (RTS) fees
•Before a drug or medical device is authorized for sale in Canada, Health Canada reviews it to assess its safety, efficacy and quality.	•Health Canada inspects establishments to assess whether they comply with regulatory requirements to conduct regulated activities related to drugs and medical devices.	•Health Canada monitors products on the Canadian market through post-market surveillance and compliance and enforcement activities.

Fees related to food and human natural health products are not part of this proposal. Health Canada will review fees for products that will be part of the Self-Care Framework, including human natural health products and over-the-counter (OTC) products.

Summary of Proposed Changes Impacting All Fees

	Current	Proposed / New
Fee Setting Ratios	Fees based on 50%-100% ratios	Fees set at 90% -100% of costs*
Annual Adjustments	2% annually	Annual fee adjustment tied to the Consumer Price Index (CPI) of previous year
Fee Mitigation	Fees waived / deferred based on individual product sales	Apply the Treasury Board Secretariat's small business definition; 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; Waiver for submission evaluation fee for products for urgent public health need; Elimination of fee deferrals
Penalty Provision	If average performance exceeds performance standards by 10% or more, the fee is reduced the following year	All individual submissions that exceed the performance standard will receive a rebate of 25%
Non-Payment of Fees	N/A	Authority to withdraw or withhold service or approval if the fee is not paid
Annual Fee Updating	Fee updates are irregular and unpredictable	Fees will be reviewed annually and adjusted accordingly; this includes decreases and increases

*Veterinary Drugs Evaluations will have a staggered increase and will be set at 75% for the first year and will then increase to 90% in the second year.

Summary of Proposed Changes for Individual Fee Lines

	Current	Proposed / New
Medical Device Evaluation Fees	Individual fees for different types of applications (i.e. fee categories)	All existing fee categories will remain unchanged, except for: • Elimination of Class IV Medical Device Applications for near patient in vitro diagnostic devices or for devices that contain human or animal tissue fee categories; these applications will be processed under the Class IV Medical Device Application category (i.e. merged into single category) New fees for Class II Amendments, Private Label Applications and Amendments
Human Drug Evaluation Fees	Individual fees for different types of submissions (i.e. fee categories)	All existing fee categories will remain unchanged, except for: • Elimination of Prescription Switch and Published Data Only fee categories; these submissions will be processed under other fee categories based on data submitted which will be more efficient New fees for the Safety Supplemental New Drug Submissions, Labelling Only (Disinfectant) and Labelling Only (Generic) submissions
Veterinary Drug Evaluation Fees	Component fees for different types of submissions (i.e. fee categories)	No change to fee categories New fee for Veterinary Health Product notification
Human Drug / Veterinary Drug Establishment Licence Fees	Complex, component based fee	Streamlined fee New fee for each foreign site
Timing of Payment of Fees	Many fees collected before review or issuance of the licence, but some invoiced part in advance and the balance after review decision	All fees collected before review begins or licence issued
Fee Payers	All Drug Identification Number (DIN) holders, Establishment Licence holders and Medical Device Licence holders	New fee payers include Radiopharmaceutical DIN holders, Active Pharmaceutical Ingredient manufacturers, veterinarians and pharmacists who import for use in animals
Performance Standards	Each existing fee has a performance standard	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) All new fee categories have a proposed service standard

	Current	Proposed / New
Performance Reporting	Annual Report (financial & performance) in departmental Results Report for all fee lines; quarterly performance report for EVAL fee lines	Quarterly and Annual reports will continue. In addition, stakeholders will be invited to meet with Health Canada representatives annually to discuss various issues surrounding the fees

Health Canada will continue to fulfill its accountability and transparency commitments when establishing fees through mechanisms such as annual public reporting, international comparisons (see Annex C), meaningful consultations, a complaint resolution process, and performance standards.

SECTION III: THE PROPOSAL

This section presents the proposed changes that affect all fee lines, as well as the individual changes to specific fee lines. International comparisons are included. A full listing of revised fee amounts and associated performance standards is presented in Annex B.

FEE SETTING RATIOS

Currently, fees for regulatory activities related to veterinary drugs, human drugs and medical devices are based on a variety of fee setting ratios (50%-100%) established when veterinary drug fees were first implemented in the mid-1990s and when human drugs and medical devices were last updated in 2011.

Proposal: As part of this fee update, it is proposed that fees for all product lines will be set as follows:

- Submission / Application Evaluation (EVAL) fees at 90% of costs*
- Establishment Licensing (EL) fees at 100% of costs
- Right to Sell (RTS) at 90% of costs

***Proposing a stepwise approach for Vet EVAL fees, with revised fees reflecting 75% of current costs as an interim measure, with increase to 90% in year two

To assist departments in establishing fees, the Treasury Board of Canada Secretariat developed a Guide to Establishing the Level of a Cost-Based User-Fee or Regulatory Charge. This guide provides direction as to how to establish appropriate fees. With this in mind, Health Canada has developed the proposed ratios based on the private benefits of market access for fee payers. For example, for the Right to Sell fees, access to the Canadian market is a significant private benefit for industry where companies can sell products in Canada to their shareholders' profit. Using this methodology, Health Canada is proposing to establish this fee at 90% of its costs.

International Comparisons

Australia's Therapeutic Goods Administration /Australian Pesticide and Veterinary Medicines Authority: The Therapeutic Goods Administration has been mandated to recover all its expenses and establishes its fees at 100% of costs. The Australian Pesticide and Veterinary Medicines Authority aims to recover 100% of regulatory fees, through a dual system of 40% of submission evaluation costs and levies based on product sales. The Australian Pesticide and Veterinary Medicines Authority also recover 100% of their costs for Good Manufacturing Practice compliance activities.

European Medicines Agency: Funded 89% by user fees, the European Medicines Agency only receives non-user fee funding to support policies for orphan and paediatric medicines, advanced therapies and micro/small/medium-sized enterprises.

United States Food and Drug Administration: Each program establishes revenue targets, and targets to collect a certain proportion from each fee line. Individual fees are calculated based on projected workload against revenue target. Appropriation funding is mandated to be maintained and/or increase each year in order to maintain access to revenues collected as user fees.

ANNUAL ADJUSTMENT

Currently, fees are adjusted by 2% every year on April 1st.

Proposal: As part of this fee update, it is proposed that the fee adjustment be tied to the Consumer Price Index (CPI). Fees will be adjusted every year by the CPI on April 1st.

This proposal mirrors the new *Service Fees Act* provision and is consistent with other international jurisdictions. Tying the fee adjustment to the CPI will allow revenues to better keep pace with the impact of inflation.

International Comparisons
Australia's Therapeutic Goods Administration/ Australian Pesticide and Veterinary Medicines Authority: Fees and charges are reviewed annually to ensure full cost recovery. Their Consumer Price Index is combined with the Wage Price Index to adjust fees. **European Medicines Agency:** Fees are adjusted each year based on the rate of inflation as published by the Statistical Office of the European Union. **United States Food and Drug Administration:** Fees are adjusted annually based on inflation and workload as authorized by the Prescription Drug User Fee Act.

MITIGATION

Currently, Health Canada provides two forms of fee mitigation measures: remissions and deferral. Remission is granted when a fee exceeds a certain percentage of an applicant's gross revenue based on product sales in Canada over a specific period of time. A deferral is granted if the applicant has not completed their first full year of operating on the day on which they file a submission or make their application, or it is the first year on the market for the product.

Health Canada recognizes that the current approach does not consider differences in a company's size, overall financial situation, primary activities, and capabilities. Nor does it encourage companies to file a drug for market authorization/sale in Canada in the event of an urgent public health need.

Proposal: As part of this fee update, it is proposed to replace existing fee mitigation and deferral measures and mitigate as follows:

- waive the first Submission / Application Evaluation (EVAL) fee for a new company that meets the Treasury Board Secretariat definition of a small business (as defined below) and if the fee is greater than $10,000, one time only
- waive the EVAL fee for certain products for urgent public health need

The revised mitigation approach will reduce strain on public funding, and enable continued access to certain drugs in response to an urgent public health need.

SMALL BUSINESS WAIVER

The department remains sensitive to the needs of small business, and that sometimes regulatory requirements can have a disproportional impact. Health Canada is proposing to use Treasury Board Secretariat's definition of a small business to determine a company's eligibility for fee mitigation:

"Any business, including its affiliates, that has fewer than 100 employees or between $30,000 and $5 million in annual gross revenues. This definition is based on commonly used definitions for what is considered a "small" business in Canada[1]."

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

In order to qualify and receive fee remission, companies will be required to provide Health Canada with:

- a breakdown of the number of persons employed for the past 12 months; and
- certified financial statements/tax filings that attest to the company's overall revenue (including affiliates).

A qualifying small business submitting their first pre-market product submission would not pay the fee if it is greater than $10k – one time only. The pre-market evaluation fees typically provide the most significant financial investment for a small business before the product is available on the market, so this waiver is expected to provide financial savings to small businesses.

Fee remission will not be available for the right to sell and establishment fee lines, regardless if they meet the definition of a small business, as the product will at that point be on the market and making sales.

International Comparisons

Australia's Therapeutic Goods Administration: There are no provisions to reduce fees based solely on the size of a company/fee payer. There are fee waivers for products that meet a regulatory definition for an orphan product and a 50% reduction in the annual manufacturing licence charge where a manufacturer's turnover is below a certain threshold.
European Medicines Agency: The Micro, Small and Medium Sized Enterprises Office was established in 2005 to manage fee incentives (reductions, exemptions and deferrals), provide regulatory assistance and training, and facilitate networking for companies that meet a regulatory definition of 'small business'. There are also fee waivers for products that meet a regulatory definition for orphan drug product, where companies pay 0-90% of the full fee.
United States Food and Drug Administration: Fees are waived or reduced to protect public health; if it poses a barrier to innovation; if the fee exceeds costs; and if the product is an orphan drug. Companies that meet a regulatory definition of 'small business' have their first submission fee waived.

ENABLING ACCESS TO CERTAIN DRUGS IN RESPONSE TO AN URGENT PUBLIC HEALTH NEED

The new *Access to Drugs in Exceptional Circumstances Regulations* (Regulations) enables access to drugs which have been authorized for sale in certain foreign jurisdictions, but are not available in Canada, to address urgent public health needs. The Regulations are intended for public health events that are exceptional in nature and that are occurring (or imminent) and require immediate action. For drugs that are eligible for importation and sale under the Regulations and on the *List of Drugs for an Urgent Public Health Need*, Health Canada will remit the pre-market drug submission fee upon receipt of a submission. The full fee payable will be required for annual payments and establishment licences.

This fee waiver is intended to provide an incentive for drug companies to submit an application to bring a drug product to the Canadian market through full regulatory channels. Future Ministerial Orders may provide additional waivers for fees under specific conditions.

PENALTIES

It is important for Health Canada and its stakeholders that the department provides timely, efficient and effective service. If performance standards are not met, an accountability mechanism needs to be in place to address missed performance.

Currently, when a performance standard (an average) is missed by 10% or greater, the department reduces its corresponding fee by the missed standard percentage for the following year for all incoming submissions/applications to a maximum of 50% of the fee, as per the requirements of the *User Fees Act*.

Proposal: As part of this fee update, it is proposed that all individual applications / licences / decisions that are not completed within the established performance standard would be rebated 25% of the fee. This method is only feasible with the inclusion of a Stop the Clock[2] provision, which pauses the performance standard count in defined circumstances.

This proposal offers increased accountability as those fee payers who experience missed performance standards will receive a reduced fee directly. It also significantly increases the predictability of the delivery of regulatory services, as each individual application is now targeted for the associated standard.

A Stop the Clock provision will increase the overall predictability of the submission / application review process, and make Health Canada accountable for active review time.

COLLABORATIVE EVALUATIONS / JOINT REVIEWS

In the event that Health Canada is a joint partner in a collaborative evaluation/joint review with other international regulatory agencies, the department will remain flexible and adaptable regarding its overall timelines and meeting performance standards. For example, veterinary drug evaluation submissions reviewed under the Regulatory Cooperation Council (RCC) may take more than a year, as data packages are submitted to the US FDA on a 'rolling' basis, rather than the complete submission at one time. Since each regulatory agency has its own performance standards and expectations, Health Canada will remain flexible operationally to continue to collaborate with international counterparts. Therefore, submissions completed as part of international cooperation initiatives will have performance standards defined and linked to those of the other countries (e.g. within one month of approval in the partnering jurisdiction).

International Comparisons

Australia's Therapeutic Goods Administration/Australian Pesticides and Veterinary Medicines Authority: The Therapeutic Goods Administration reduces fees by 25% if submission performance standards are missed. A stop the clock provision is in place that allows for a predictable pause in submission review as well as the possibility of a mutually agreed-upon pause. There are no penalties for missed standards associated with establishment licencing. The Australian Pesticide and Veterinary Medicines Authority do not have a financial penalty model for missed performance standards.
European Medicines Agency & United States Food and Drug Administration: There is no direct financial accountability to individual fee payers if performance standards are not met.

NON-PAYMENT OF FEES

Currently, Health Canada does not have the authority to withdraw or withhold services as a result of non-payment issues for fees charged in existing regulations. With the new authorities provided through the *Budget Implementation Act*, the Minister of Health can withdraw or withhold services in the event of non-payment of fees fixed under the *Food and Drugs Act*.

[2] Health Canada will be developing a Policy on Stop the Clock for cost recovery performance reporting across all fee lines. Stakeholders will be engaged in its development.

The department will be implementing[3] its new authority to withdraw or withhold a service, the use of a facility, a regulatory process or approval or a product, right or privilege from any person who fails to pay the fixed fee.

This authority will strengthen the business model of the cost recovery regime and support the appropriate use of resources.

International Comparisons

Australia's Therapeutic Goods Administration/ Australian Pesticide and Veterinary Medicines Authority: Submissions are not considered complete and are not accepted for review until the fee has been paid.
European Medicines Agency: The executive director may either not provide or suspend the services requested until the relevant fee has been paid.
United States Food and Drug Administration: Submissions are not considered complete and are not accepted for review until the fee has been paid.

PERFORMANCE STANDARDS

Currently, each existing fee has a related performance standard. The department publishes its performance against current standards annually in the departmental Results Report (DRR). The performance reported in the DRR is currently used to determine if fee penalties are to be applied.

As part of this fee update, it is proposed that existing performance standards will be maintained unless noted otherwise, and that all new fees have an appropriate service standard (details are presented in Annex B). Existing and proposed performance standards are generally internationally comparable, and reflect the Department's costs and ability to deliver service. Performance will continue to be reported in the DRR.

PERFORMANCE REPORTING

Health Canada understands that accountability is paramount in its relationship with stakeholders. Currently, the department can provide quarterly and annually reports on its performance should stakeholders request it.

Moving forward, Health Canada will further strengthen its relationship with stakeholders and it is proposed that every year the department will invite stakeholders to meet and discuss areas of interest associated with the fees including cost containment measures.

ADDITIONAL FEE SPECIFIC CHANGES

MEDICAL DEVICE FEES

A full listing of revised fee amounts and associated performance standards is presented in Annex B.

MEDICAL DEVICE LICENCE APPLICATION (MDEVAL)

In order to sell certain medical devices in Canada the manufacturer needs to obtain a product licence. There are four classes of medical devices in Canada: Class I devices present the lowest potential risk and Class IV devices the greatest potential risk.

Fees are charged to evaluate the required documentation submitted by a manufacturer to demonstrate the safety, efficacy and quality of a product for specific conditions of use.

[3] Details of this process will be included in Guidance Documents

Proposal: As part of this fee update, it is proposed that the Medical Device Licence Application fee line change as follows:

- introduce new fee categories for Class II Licence Amendments and Private Label Applications and Amendments with appropriate performance standards
- eliminate Class IV Medical Device Applications for near patient in vitro diagnostic devices or for devices that contain human or animal tissue fee categories
- require full payment of fee before review/processing begins

Class II Licence Amendments: The establishment of a new Class II Medical Device Licence Amendment fee line is being proposed to reflect significant workload and associated costs that are currently not being recovered. The new service standard will be 15 days.

Class IV Licence Applications: Consolidation of all licence applications for Class IV medical devices into a single fee category, including those that contain human or animal tissue and for near-patient in vitro diagnostic devices is being proposed. This will reduce administrative burden and address the low submission volumes of near-patient in vitro diagnostic applications. The 75-day service standard will remain.

Private Label Applications and Amendments: Currently, private label applications for medical devices are exempt from paying fees. A fee to cost recover the administrative effort for processing private label licence applications and amended licence applications for Class II, III and IV medical devices is being proposed, given that the department receives a substantial number of private label applications that require significant resources. The new service standard will be 15 days.

Timing: Currently the timing of fee payments for medical device applications can either be full payment up front (if the fee is less than $5k), or staggered (75% payable once accepted for review and 25% when review is completed).

Health Canada is proposing to invoice the full fee (100%) to the manufacturer for the application once it is accepted or approved for review.[4] If an application is rejected at screening, it would be invoiced for 10% of the full fee to cover the costs associated with screening the submission (as per the current process). This change will simplify billing processes and align with the current practices of other international regulators.

International Comparisons

Australia's Therapeutic Goods Administration: Full payment of a fee is required to release an application for processing.
European Medicines Agency: Requires 100% of the fee once an application have been approved for review.
United States Food and Drug Administration: Requires 100% of fees at the time of application submission.

MEDICAL DEVICE ESTABLISHMENT LICENCING (MDEL)

Establishment licence fees are charged to review applications for new licences and for the renewal of licences. These fees include compliance activities such as facility inspections that verify the compliance of establishments needed to engage in production and distribution of medical devices. Current licencing requirements remain unchanged[5].

[4] Class II applications will continue to submit their fee with their application.
[5] Medical device distributors and importers must secure an MDEL regardless of device classification. Manufacturers of Class I medical devices planning to sell directly into Canada without a distributor must secure an MDEL. Manufacturers of class II, III and IV devices are

Proposal: As part of this fee update, it is proposed that fees associated with the Medical Device Establishment Licencing will be decreased to reflect updated costs. All licence holders will be required to pay this fee.

MEDICAL DEVICE RIGHT TO SELL (MDRTS)

Health Canada monitors medical devices on the Canadian market through post-market surveillance, compliance and enforcement oversight, policy and technology development, quality management oversight, and product testing and laboratory analysis. Industry pays an annual fee for the right to maintain and sell medical devices in Canada, except those classified as Class I, which are medical devices with the lowest risk.

There are no proposed changes to the Medical Device Right to Sell fee structure, scope or performance standard.

HUMAN DRUG FEES

A full listing of revised fee amounts and associated performance standards is presented in Annex B.

DRUG SUBMISSION EVALUATION (DEVAL)

Before a drug is authorized for sale in Canada, Health Canada reviews it to assess safety, efficacy and quality. Drug products include prescription and non-prescription pharmaceuticals, biologics, disinfectants and sanitizers with disinfectant claims.

Proposal: As part of this fee update, it is proposed that the Drug Submission Evaluation fee line change as follows:

- introduce new fee categories for Labelling Only (Generic), Labelling Only (Disinfectants) and Safety Updates to Labelling (each with a 120 day standard)
- eliminate Published Data and Rx Switch fee categories
- revise performance standard for Labelling Only Div.1 (180 days to 120 days); Div.8 (60 days to 120 days) and DINA Labelling Standard (45 days to 60 days)
- require full payment of fee before review/processing begins

The fee category definitions for drug submission will be revised to better reflect the regulatory requirements and accurate costs of program delivery. Specifically, changes are proposed to better align with the requirements and obligations imposed by recent amendments to the *Food and Drugs* Act (Vanessa's Law) and Plain Language Labelling regulatory amendments as well as recently updated guidance on issues such as Submissions Relying on Third Party Data and Administrative Submissions.

New fee for submissions previously categorized as Safety Notifiable Changes (NCs): Safety NCs will no longer be accepted and instead information will be filed through Supplemental (Abbreviated) New Drug Submissions (S(A)NDSs). As it stands currently, the department has been reviewing this work but not cost recovering for it. Moving forward, for brand products, sponsors will file safety updates using the new fee category "Clinical or non-clinical data only, in support of safety updates to the labelling" or "Labelling Only" in cases where no supporting data is required. For generic products, depending on the information submitted, sponsors may file either as "Labelling Only" (if their labelling differs from that of the Canadian Reference Product (CRP) and/or a

exempt from MDEL requirements for the devices they sell under their own name (i.e. those for which they hold a device license). However, if the manufacturer chooses instead to sell through distributors in Canada, the distributors are required to have an MDEL.

label review is required) or using the new fee category “Labelling only to be in line with CRP” (only if the generic has updated the Safety & Efficacy information verbatim to the CRP, and no additional label review is required). The new categories will have a performance standard of 120 days, to be consistent with the level of effort.

New fee for Disinfectant (Labelling Only) submissions: This fee is for submissions in support of a manufacturer and/or product name change that requires a review of labelling material due to deviations from the previously authorized labelling and/or product (e.g. for licencing agreements against ‘master’ disinfectant drug labels). The new category will have a performance standard of 120 days, to be consistent with the level of effort.

New Performance Standards for Labelling Only and DINA Labelling Standard fee categories: The performance standard of the existing Labelling Only fee category (Division 8) will change from 60 days to 120 days to be consistent with the level of effort as per Plain Language Labelling regulatory requirements. In addition, the Division 1 submissions will change from 180 days to 120 days to remain consistent within the Labelling Only fee line. The DINA Labelling submission standard will change from 45 days to 60 days.

Elimination of Published Data Only fee category: The Published Data Only fee category submissions will be eliminated and instead Health Canada will process published data submissions in the most appropriate existing fee category that reflects comparable effort (e.g. Clinical or non-clinical data and chemistry and manufacturing data). The reason for this elimination is that currently, the Published Data Only fee category is being used for more complex submissions that originally intended and the fee does not reflect the level of effort.

Elimination of Switch from Prescription (Rx) to Non-Prescription (OTC) Status fee category: Most Rx to OTC submissions were already being included in other fee categories, reflecting the appropriate level of effort for the submission data packages. This fee category was created in 2011 specifically for switch submissions for the same condition of use (exact same product) which did not appear to fit well in any other fee category. An exceptionally low number of submissions in this category, paired with data analysis which showed level of effort is in fact commensurate with other categories, has resulted in the proposal to eliminate this fee category. Instead, Health Canada will process these submissions in the most appropriate (data and level of effort) existing fee category.

Revisions to Fee Category Descriptions: Several fee class descriptions (e.g. Comparative Studies, Administrative Submissions) are being revised to better reflect the submission information requirements and/or scope of the fee category. These changes will better explain the type of submission and the requirements needed thus allowing industry to better understand what is required.

As per the current fee structure, the same fee will be charged for biologic and pharmaceutical submissions, most service standards will remain unchanged (exceptions are listed above) and performance will continue to be reported by program and submission type, and also by individual submission.

Timing: Currently the timing of fee payments for drug submissions can either be full payment up front (if fee is less than $10k), or staggered (75% payable once accepted for review and 25% when review is completed).

Health Canada is proposing to invoice the full fee (100%) to the manufacturer for the application once it is accepted or approved for review. If an application is rejected at screening, it would be invoiced for 10% of the full fee to cover the costs associated with screening the submission (as per the current process). This change will simplify billing processes and align with the current practices of other international regulators.

International Comparisons
Australia's Therapeutic Goods Administration: Full payment of a fee is required to release an application for processing. **European Medicines Agency:** Requires 100% of the fee once an application have been approved for review. **United States Food and Drug Administration:** Requires 100% of fees at the time of application submission.

DRUG ESTABLISHMENT LICENCE (DEL)

DEL fees are charged to review applications for new licence and for the renewal of licences. These activities include compliance activities such as inspections of facilities that fabricate, import, wholesale, distribute, package, label or test drugs. Like the medical device establishment licence fee, this fee covers activities related to facilities rather than the products themselves.

Proposal: As part of this fee update, it is proposed that the Drug Establishment Licence fee structure be streamlined to better associate fees with activity costs and to simplify fee calculations.

The new DEL fee structure has two components:

1. The annual licence review fee, which will be calculated based on each establishment's activities. Companies will be charged a fee for the activity that involves the highest level of risk and effort for Health Canada, and consequently creates the greatest cost, of those activities for which the facility is licenced; and,
2. The foreign building fee, which will be calculated per foreign building listed on the Drug Establishment Licence.

The provision related to medical gas packaging and labelling facilities will no longer be applicable; medical gas facility fees will be charged the same fee to those of other drug facilities.

DRUGS RIGHT TO SELL (DRTS)

Health Canada monitors human drugs on the Canadian market through post-market surveillance and compliance and enforcement oversight, policy and technology development, quality management oversight, product testing and laboratory analysis. Industry pays an annual fee for the right to maintain and sell human drugs in Canada.

Proposal: As part of this fee update, it is proposed that the Drug Right to Sell performance standard be changed to 20 days from 120 days.

The performance standard will be changed to 20 calendar days to update the Drug Product Database following receipt of a complete Annual Notification, down from the current 120 days, based on historical performance.

While currently exempt from paying this fee, manufacturers of Schedule C drugs would be charged the DRTS fees once the revised fees are implemented.

The costing for this fee line includes activities that were not previously fully funded under cost recovery such as border integrity, Active Pharmaceutical Ingredient compliance verification, drug shortages, pharmacovigilance compliance and enforcement and IT investments. For additional information, see Annex A.

VETERINARY DRUG FEES

Current veterinary drug activities are conducted under the *Food and Drug Regulations*. These activities are supported by three fee categories including, Drug Evaluations, Right to Sell and Establishment Licensing fees. These activities are supported by categories with multiple fee lines that are component based.

Fees related to veterinary drugs have not been updated since their original implementation in 1995-98. Since the introduction of these fees, the veterinary regulatory program has implemented changes that have significantly strengthened service delivery:

- Innovation-supportive regulatory environment leading to increased access to products, including low risk veterinary health products;
- Improvement in the management of submissions (faster review time and improvement in process efficiencies);
- Increased collaboration with international regulatory agencies for simultaneous /joint reviews;
- Enhanced communication with companies and foreign regulatory agencies;
- Increased availability of reviewers for scientific input, advice and discussions with companies;
- Greater predictability for the industry;
- Addition of performance standards;
- A new regulatory framework to address antimicrobial resistance; and
- Several program transformations to better focus good manufacturing practice inspections and surveillance activities where higher risks have been identified, including in foreign establishments.

A full listing of revised fee amounts and associated performance standards is presented in Annex B.

VETERINARY DRUGS EVALUATION (VET EVAL)

Before a veterinary drug is authorized for sale in Canada, Health Canada reviews it to assess its efficacy animal and human safety and quality. Currently, Health Canada is recovering approximately 15% of costs for veterinary drug submissions.

Proposal: As part of this fee update, it is proposed that Veterinary Drugs Evaluation fees be changed as follows:

- a stepwise approach with revised fees reflecting 75% of current costs as an interim measure, with an increase to 90% in year two
- introduce a notification fee for Veterinary Health Products (30 day performance standard)
- require full payment of fee before review/processing begins

Stepwise fee-setting ratio: The intention is to achieve a fee setting ratio for all EVAL fees of 90%. However, Health Canada recognizes the burden on the veterinary drug industry of such a significant increase in fees. As a result the department is introducing a stepwise approach for Vet EVAL fees, with the first revised fees reflecting 75% of current costs in the first year. Fees will be subsequently increased to 90% in Year 2.

Veterinary Health Products (VHPs): Through a pilot product launched in 2012, VHPs have been notified and sold in Canada by a third party administrator. Through this program, notifiers are paying both registration and annual fees to the third party.

In November, regulatory amendments to the *Food and Drug Regulations* will come into force which will require all VHPs to be subject to a notification process and post-market surveillance including reporting of adverse

events by Health Canada. After November 2017, these VHPs will be reviewed and processed by Health Canada and consequently a new fee is being proposed and will have a performance standard of 30 days.

Emergency Drug Release (EDR) program and Experimental Studies Certificates (ESCs): The EDR program provides access to unapproved drug in situations where there are no alternatives and for emergencies. The ESCs provide access to unapproved drugs for research development and clinical trials conducted in Canada. These fee lines will not be increased as part of this fee proposal.

Timing: Currently the timing of fee payments for drug submissions can either be full payment up front (if fee is less than $10k), or staggered (75% payable once accepted for review and 50% when review is completed).

Health Canada is proposing to invoice the full fee (100%) to the manufacturer for the application once it is accepted or approved for review. If an application is rejected at screening, it would be invoiced for 10% of the full fee to cover the costs associated with screening the submission (as per the current process). This change will simplify billing processes and align with the current practices of other international regulators.

International Comparisons
Australian Pesticides and Veterinary Medicines Authority: Full payment of a fee is required to release an application for processing. **European Medicines Agency:** Requires 100% of the fee once an application has been approved for review. **United States Food and Drug Administration:** Requires 100% of fees at the time of submission application.

VETERINARY DRUGS ESTABLISHMENT LICENCING (VET EL)

Currently, Veterinary Drugs Establishment Licencing fees align with the Drugs Establishment Licencing fees from their original implementation in 1998.

Proposal: As part of this fee update, it is proposed that Veterinary Drugs Establishment Licencing fees will be revised as per fees for human drug establishment licences as presented above (i.e., the same fees will be charged regardless whether establishments manage veterinary drugs or human drugs).

Since compliance oversight is similar for these products, these two fee lines will be treated identically. This will not only better align fees with activity costs, it will also allow Health Canada to more effectively respond to the increased compliance and enforcement requirements of the new antimicrobial resistance (AMR) regulations. It is also recognized that there will be new fee payers for this fee line, as a result of the AMR regulations (e.g. veterinarians and pharmacists who import drugs for use in animals).

If an establishment is responsible for both human drug and veterinary drug activities, it will only be charged one fee that is in respect of activities for both types of drugs.

VETERINARY DRUGS RIGHT TO SELL (VET RTS)

Health Canada monitors veterinary drugs on the Canadian market through post-market surveillance and compliance and enforcement oversight, policy and technology development, quality management oversight, product testing and laboratory analysis. Industry pays an annual fee for the right to maintain and sell veterinary drugs in Canada.

Proposal: As part of this fee update, it is proposed that the Veterinary Drugs Right to Sell performance standard be changed to 20 days.

The performance standard will be changed to 20 calendar days to update the Drug Product Database following receipt of a complete Annual Notification, down from the current 120 days based on historical performance.

SECTION IV: CONCLUSION AND NEXT STEPS

The updates outlined throughout this document reflect costs for providing services to industry, align with the cost recovery practices of international counterparts and relieve the Canadian taxpayer of the burden of subsidizing activities for which industry receives direct benefits. These proposed changes will provide stable and sustainable resourcing for Health Canada's regulatory programs thus ensuring that the department can continue to provide reliable service to industry while continuing to serve Canadians.

NEXT STEPS

Stakeholders are invited to provide feedback on this document via the generic email account CRI_IRC_Consultations@hc-sc.gc.ca by January 4, 2018.

ANNEX A: COSTING

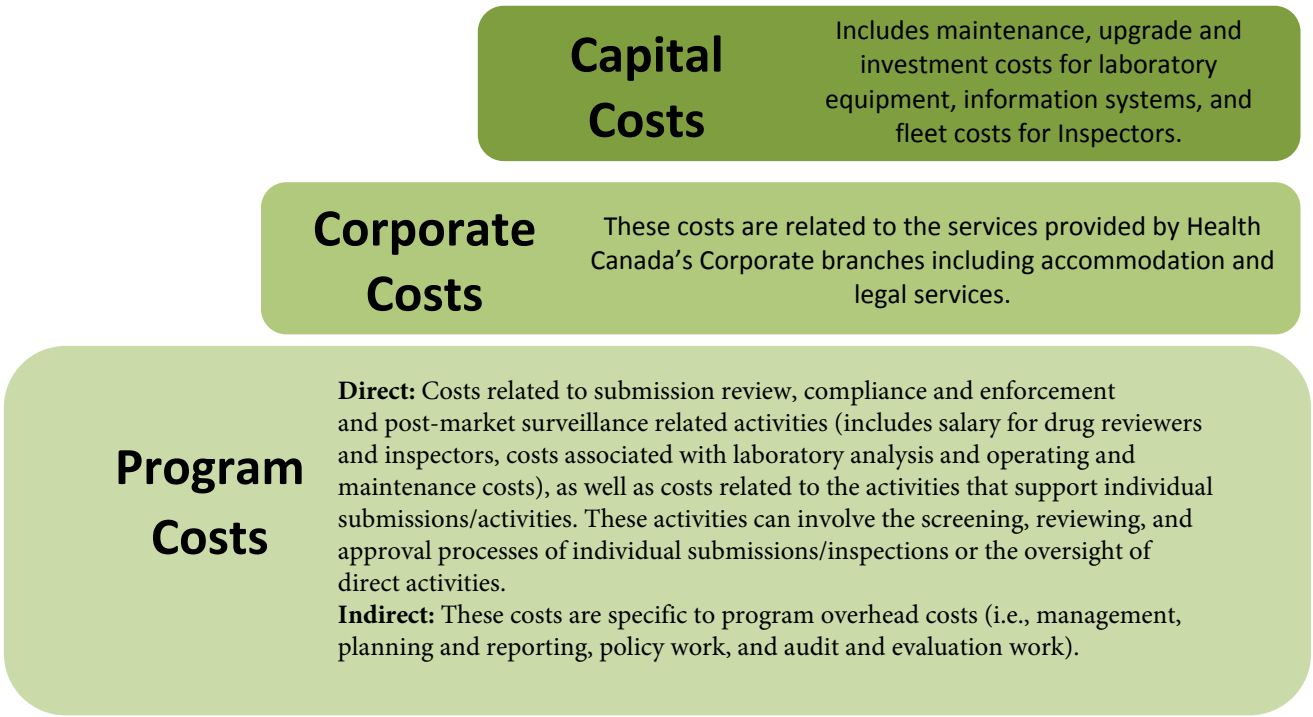
COSTING DATA

Health Canada is using an integrated approach to determine costs for program activities. It has implemented a program-wide time tracking system (the Cross-Application Timesheet – Project System; CATS-PS) to collect level of effort by activity including tracking time spent reviewing individual submissions and applications. This system allows both direct program costs and indirect program costs to be assigned to activities based on their use of resources. The department has also developed and implemented a detailed activity structure that provides consistent definitions of key activities to allow for costs to be compared across programs and product lines. The information contained in both the activity structure and time tracking systems are aligned with the data in the departmental Financial System (SAP), which allows for more accurate mapping. The information from these structures and systems was used to establish and validate the proposed new fees.

COSTING METHODOLOGY

In conducting this activity based costing exercise, Health Canada respected the Treasury Board Secretariat's Guidelines on Costing and determined total costs per fee line.

The total costs were determined by totalling the costs described above (program direct and indirect costs, corporate costs, and capital costs). A costing model was developed that maps costs to specific activities within a branch, and allows Health Canada to calculate fully loaded costs by fee line. There were four complete years of data available from the time tracking system, so the complete data set was analyzed. These total costs include both the direct costs in support of actual submissions and applications as well as indirect costs proportionally applied to those activities. Direct service support costs were allocated proportionally to all activities within the associated fee. Program indirect costs are allocated proportionally to all activities within the given program. Branch overhead and corporate costs are allocated proportionally to all activities across the programs.



EVALUATION FEES

Activities such as individual submission review, submission screening and processing, submission coordination and management, and scientific/technical management are included in these fee lines.

For pre-market authorization fees based on human drugs and medical device submission and application reviews, an hourly rate was determined using the costing method described above as well as the volume and average time spent on submissions within each fee activity. This data was based on all submissions received and completed between April 2013 and March 2016. The hourly rate for each fee line was determined by dividing the total costs by the calculated total direct hours spent on each fee line. To arrive at the unit costs for each fee line the hourly rate was multiplied by the mean sample hours required to complete a submission.

There are challenges associated with costing the veterinary drug submission evaluation fee line. Although all staff report all their time in the SAP PS time tracking system, and level of effort is recorded against each individual veterinary drug submission, data is not tracked against the individual submission components that are used to assess the associated fee. As a result, a slightly modified costing approach was taken for this fee line, where the overall costs of program delivery were determined and then factored against the submission components. As the fees were not increased in 2011 and have never been revised, they are significantly outdated, being based on original program delivery and costs from the mid-nineties.

ESTABLISHMENT LICENSING FEES

Activities including domestic and foreign building inspections and licensing/billing activities for active pharmaceutical ingredients (APIs), finished dosage form (FDF) drugs, veterinary drugs and medical devices are included in these fee lines.

For medical device establishment licensing fees, the total costs of all activities under that fee line were calculated then divided by the number of medical device establishment licences.

For drug establishment licensing fees, the total costs of all activities under that fee line were calculated then allocated proportionally per facility under each establishment licence by activity type. Facility activity types include: sterile fabricator, fabricator, packager/labeller, importer, distributor, wholesaler, and tester. The foreign building component of the establishment licensing fee was determined by calculating the cost of activities related to the regulatory oversight of foreign buildings and distributing that cost between foreign buildings listed on establishment licences.

RIGHT TO SELL FEES

Activities such as compliance verification, border integrity maintenance, compliance promotion and post-market surveillance are included in these fee lines.

For each product line (human drugs, veterinary drugs and medical devices) the total costs of all activities were calculated then divided by the total number of annual product notifications.

ANNEX B: FEES AND PERFORMANCE STANDARDS

Medical Device Licence Application Review

Name of Fee	Description	Current Fee	New Fee	Current Performance Standard	New Performance Standard
Class II – Licence Application	Class II Medical Device Licence Application	$397	$627	15 calendar days to process application	No change
Class II – Licence Amendment	Class II Medical Device Licence Amendment Application	$0	$320	15 calendar days to process application	No change
Class III – Licence Application	Class III Medical Device Licence Application	$5,691	$13,861	60 calendar days to complete Review 1	No change
Class III – Licence Application (near patient)	Class III Medical Device Licence Application for a near patient in vitro diagnostic device	$9,687	$32,267	60 calendar days to complete Review 1	No change
Class III – Changes in Manufacturing	Changes in manufacturing processes, facility, equipment or quality control procedures	$1,433	$9,956	60 calendar days to complete Review 1	No change
Class III – Significant Changes	Class III Significant Changes (not related to manufacturing)	$5,330	$11,127	60 calendar days to complete Review 1	No change
Class IV – Licence Application	Class IV Medical Device Licence Application	$12,347 - $22,560	$30,063	75 calendar days to complete Review 1	No change
Class IV – Changes in Manufacturing	Change referred to in paragraph 34(a) of the Medical Devices Regulations that relates to manufacturing	$1,433	$7,584	75 calendar days to complete Review 1	No change
Class IV – Significant Change (not related to Manufacturing)	Any other change referred to in paragraph 34(a) or (b) of the Medical Devices Regulations	$6,073	$15,907	75 calendar days to complete Review 1	No change
Private Label Applications and Amendments	New and amended licence applications for private label medical devices	$0	$172	15 calendar days to process application	No change

Medical Device Establishment Licence

Name of Fee	Description	Current Fee	New Fee	Current Performance Standard	New Performance Standard
Medical Device Establishment Licence	Applications for new and renewal of licences.	$8,109	$4,500	120 calendar days to issue licence	No change

Medical Device Right to Sell

Name of Fee	Description	Current Fee	New Fee	Current Performance Standard	New Performance Standard
Medical Device Right to Sell	Annual fee for the right to maintain a medical device on the Canadian market.	$375	$500	20 days to update Medical Device Licence Listing database following receipt of a complete Annual Notification	No change

Human Drug Submission Review (Pharmaceutical, Biologics, OTC)

Name of Fee	Description	Current Fee	New Fee	Current Performance Standard	New Performance Standard
New Active Substance	Submissions in support of a drug, excluding 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.	$341,770	$603,619	300 calendar days to complete Review 1	No change
Clinical or Non-Clinical Data and Chemistry & Manufacturing	Submissions based on clinical or non-clinical data and chemistry and manufacturing data for a drug that does not include a new active substance.	$173,106	$312,562	Div.1 210 calendar days Div.8 300 calendar days to complete Review 1	No change

Name of Fee	Description	Current Fee	New Fee	Current Performance Standard	New Performance Standard
Clinical or Non-Clinical Data Only	Submissions based only on clinical or non-clinical data for a drug that does not include a new active substance.	$80,794	$124,979	Div.1 210 calendar days Div.8 300 calendar days to complete Review 1	No change
Comparative Studies	Submissions based on comparative bioavailability, pharmacodynamic, or clinical studies with or without chemistry and manufacturing data for a drug that does not include a new active substance.	$48,834	$70,435	Div.1 210 calendar days Div.8 180 calendar days to complete Review 1	No change
Chemistry & Manufacturing Data Only	Submissions based only on chemistry and manufacturing data for a drug that does not include a new active substance.	$23,089	$43,335	Div.1 210 calendar days Div.8 180 calendar days to complete Review 1	No change
Clinical or non-clinical data only, in support of safety updates to the labelling	Submissions based only on clinical or non-clinical data, for a drug that does not include a new active substance, that propose safety updates to the labelling material	$0	$22,871	120 calendar days	120 calendar days to complete Review 1
Labelling Only	Submissions of labelling material, including data in support of a brand name assessment, standardized /published test methods or in vitro/in vivo photostability data or changes to brand names for non-prescription DIN applications, (but not including other supporting clinical or non-clinical data, comparative data, or chemistry and manufacturing data); not applicable to disinfectants or submissions that attest to a labelling standard.	$3,111	$6,298	Div.1 180 calendar days Div. 8 60 calendar days to complete Review 1	120 calendar days to complete Review 1
Labelling Only (Generic)	Submissions in support of changes to the labelling to	$0 / $3,111	$2,626	90 calendar days / 60	120 calendar days to

Name of Fee	Description	Current Fee	New Fee	Current Performance Standard	New Performance Standard
	be in line with the Canadian Reference Product, that do not include any additional labelling updates requiring a labelling assessment			calendar days to complete Review 1	complete Review 1
Administrative Submission	Submissions in support of a change in the manufacturer's name and/or product name following changes in product ownership, a merger or buy-out; when manufacturers request an additional product name (same product and supplier); and, when two manufacturers enter a licencing agreement (includes post-authorization label changes filed by licencees to remain identical to licensor's product and post-authorization Chemistry and Manufacturing Updates (CMC) for products regulated under Schedules C and D of the Regulations) that do not require a review of labelling material or brand name.	$324	$1,401	45 calendar days to complete Review 1	No change
Disinfectant – Full Review	Submissions and applications that include data in support of a disinfectant. (more than labelling only)	$4,305	$16,214	Div.1 180 or 210 calendar days Div.8 300 calendar days to complete Review 1	No change
Labelling Only (Disinfectant)	Submissions in support of a manufacturer and/or product name change that requires a review of labelling material due to deviations from the previously authorized labelling and/or product (e.g., for licencing agreements against "master" disinfectant drug	$325 (previously processed as Administrative submissions)	$2,948	90 calendar days to complete Review 1	120 calendar days to complete Review 1

Name of Fee	Description	Current Fee	New Fee	Current Performance Standard	New Performance Standard
	labels).				
Drug Identification Number Application – Labelling Standard	Applications that attest to 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. Requires Label review and brand name assessment (does not include data in support of a brand name assessment).	$1,726	$1,901	45 calendar days to complete Review 1	60 calendar days to complete Review 1

Drug Establishment Licences (human drug and veterinary drug)

Name of Fee	Description	Current Fee (average)	New Fee	Current Performance Standard	New Performance Standard
Annual Licence Review	Applications for new and renewal of licences.			250 calendar days to issue licence	No change
Sterile Fabricator		$39,125	$41,114		
Non-Sterile Fabricator		$24,156	$30,481		
Packager / Labeller		$14,055	$5,942		
Importer		$24,202	$31,745		
Distributer		$10,588	$16,202		
Wholesaler		$3,721	$9,851		
Tester		$1,928	$27,109		
Foreign Site (each)		$1,715	$900		

Drug Right to Sell

Name of Fee	Description	Current Fee	New Fee	Current Performance Standard	New Performance Standard
Drug Right to Sell	Annual fee for the right to maintain a drug product on the Canadian market	$1,152	$4,587	120 calendar days to update Drug Product Database following receipt of a complete Annual Notification	20 calendar days to update Drug Product Database following receipt of a complete Annual Notification

Veterinary Drug Submission Evaluation

	Description	Current Fee	New Fee (Year 1 @ 75%)	New Fee (Year 2 @ 90%)	Current Performance Standard	New Performance Standard
	Veterinary Health Product Notification	Presently these products are administered via a third party notifier	$714	$857	n/a	30 calendar days to review
	New Drug Submissions (NDS)				300 calendar days to complete Review 1	No change
1	Efficacy & safety data (intended species) for one route, dosage form & indication in 1 species. For antiparasitic, several indications in 1 food species.	$15,980	$79,900	$95,880		
2	Efficacy & safety data (intended species) for one route & dosage form for an antiparasitic in 1 non-food species	$9,680	$48,400	$58,080		
3	Efficacy & safety data (intended species) for one route, dosage form & indication in 2 species; or one route, dosage form & 2 indications in 1 species.	$23,240	$116,200	$139,440		
4	Efficacy & safety data (intended species) for a growth promotion or production enhancement indication in 1 species.	$31,470	$157,350	$188,820		
5	Comparative (pharmacodynamic, clinical or bioavailability) data for additional route. (In addition to route referred to in item 1, 2 or 3.	$2,900	$14,500	$17,400		
6	Comparative (Pharmacodynamic, clinical or bioavailability) data for each additional strength. (1 study to support strengths may be included with a NDS, under items 1, 2 or 3, without payment of this fee.)	$480	$2,400	$2,880		
7	For food animals, toxicity, metabolism & residue depletion studies to establish an ADI with a SF of 1,000, a	$21,790	$108,950	$130,740		

	Description	Current Fee	New Fee (Year 1 @ 75%)	New Fee (Year 2 @ 90%)	Current Performance Standard	New Performance Standard
	MRL & a withdrawal period for one dosage form, dosage & route in 1 species.					
8	For food animals, toxicity, metabolism & residue depletion studies to establish an ADI with a SF of <1,000, a MRL & a withdrawal period for one dosage form, dosage & route in 1 species.	$29,050	$145,250	$174,300		
9	For food animals, residue depletion studies to establish a withdrawal period for an additional dosage form, dosage or route.	$2,900	$14,500	$17,400		
10	For food animals (once an ADI and a SF of # 1,000 has been established), metabolism & residue depletion studies to establish a MRL & a withdrawal period for one dosage form, dosage and route in an additional species.	$14,520	$72,600	$87,120		
11	Chemistry & manufacturing for non-compendial medicinal ingredient. (A medicinal ingredient previously evaluated within the last 3 years, to which reference is made is not required to be reevaluated).	$4,840	$24,200	$29,040		
12	Chemistry & manufacturing for one strength of 1 dosage form	$4,840	$24,200	$29,040		
13	Chemistry & manufacturing for an additional strength of 1 dosage form submitted with item 12.	$2,420	$12,100	$14,520		
14	Change in manufacturer of a drug. (Applies only where a NDS does not include any of the above components.)	$250	$1,250	$1,500		
	Supplement to a New Drug Submission (SNDS)				240 calendar days to complete Review 1	No change
1	Efficacy data for an additional indication in 1 species.	$12,590	$62,950	$75,540		

	Description	Current Fee	New Fee (Year 1 @ 75%)	New Fee (Year 2 @ 90%)	Current Performance Standard	New Performance Standard
2	Efficacy & safety data (intended species) for one route & dosage form for an antiparasitic in 1 non-food species.	$9,680	$48,400	$58,080		
3	Efficacy & safety data (intended species) for an indication in another species.	$15,980	$79,900	$95,880		
4	Efficacy & safety data (intended species) for one route, dosage form & indication in 2 species; or one route, dosage form & 2 indications in 1 species.	$23,240	$116,200	$139,440		
5	Efficacy & safety data (intended species) for a growth promotion or production enhancement indication in 1 species.	$31,470	$157,350	$188,820		
6	Efficacy & safety data (intended species) for the concurrent use of 2 drugs approved for the same species.	$7,740	$38,700	$46,440		
7	Comparative (pharmacodynamic, clinical or bioavailability) data for an additional route. (In addition to route referred to in item 2 or 4.)	$2,900	$14,500	$17,400		
8	Comparative (pharmacodynamic, clinical or bioavailability) data for each additional strength. (1 study to support strengths may be included with a SNDS, under item 1, 2 or 3 without payment of this fee.)	$480	$2,400	$2,880		
9	For food animals, residue depletion studies to establish a new withdrawal period for a change in the dosage or route of an approved dosage form in 1 species.	$2,900	$14,500	$17,400		
10	For food animals, metabolism & residue depletion studies to establish a MRL & a withdrawal period for one dosage & route of an approved dosage form in an additional species.	$14,520	$72,600	$87,120		
11	For food animals, toxicity	$7,260	$36,300	$43,560		

	Description	Current Fee	New Fee (Year 1 @ 75%)	New Fee (Year 2 @ 90%)	Current Performance Standard	New Performance Standard
	studies for a change of an established ADI, MRL & withdrawal period.					
12	For concurrent use of 2 drugs in a food species, residue depletion studies to determine if extension to withdrawal periods is required.	$5,810	$29,050	$34,860		
13	Chemistry & manufacturing for change in source of noncompendial medicinal ingredient or its manufacturing process.	$4,840	$24,200	$29,040		
14	Chemistry & manufacturing for change in formulation or dosage form.	$2,420	$12,100	$14,520		
15	Chemistry & manufacturing for change in packaging or sterilization.	$1,930	$9,650	$11,580		
16	Chemistry & manufacturing for extension of expiry date.	$1,450	$7,250	$8,700		
17	Chemistry & manufacturing for concurrent use of 2 drugs.	$1,450	$7,250	$8,700		
18	Chemistry & manufacturing for change in manufacturing site (parenteral or sterile).	$480	$2,400	$2,880		
19	Change in manufacturer or brand name of a drug. (Applies only where a SNDS does not include any of the above components.)	$250	$1,250	$1,500		
	Abbreviated New Drug Submission (ABS) or Supplement to an Abbreviated New Drug Submission (SABS)				ABS = 300 calendar days to complete Review 1 SABS = 240 calendar days to complete Review 1	No change
1	Comparative (pharmacodynamic, clinical or bioavailability) data for one route & dosage form.	$2,900	$14,500	$17,400		
2	For food animals, residue depletion studies to confirm that the withdrawal period(s) for each species falls within the conditions of use for the	$2,900	$14,500	$17,400		

	Description	Current Fee	New Fee (Year 1 @ 75%)	New Fee (Year 2 @ 90%)	Current Performance Standard	New Performance Standard
	Canadian reference product.					
3	Chemistry & manufacturing for non-compendial medicinal ingredient. (A medicinal ingredient previously evaluated within the last 3 years, to which reference is made is not required to be re-evaluated.)	$4,840	$24,200	$29,040		
4	Chemistry & manufacturing for 1 dosage form.	$4,840	$24,200	$29,040		
5	Change in manufacturer or brand name of a drug. (Applies only where an abbreviated submission does not include any of the above components.)	$250	$1,250	$1,500		
	DIN Application				120 calendar days to complete Review 1	No change
1	Information (other than item 2 below) for DIN application, including the submission of labelling for a second review, if required.	$720	$3,600	$4,320		
2	Published references or other data.	$500	$2,500	$3,000		
3	Change in manufacturer or brand name of a drug. (Applies only where a DIN application does not include any of the above components.)	$250	$1,250	$1,500		
	Preclinical (Investigational) New Drug Submission (IND)				60 calendar days to review application	No change
1	Efficacy & safety data (intended species) & protocol for the conduct of clinical studies for one dosage form, route & indication in 1 species.	$4,840	$24,200	$29,040		
2	Efficacy data & protocol for the conduct of clinical studies for one route & indication with a dosage form for which a NOC has been issued for use in that species.	$3,870	$19,350	$23,220		
3	For food animals, toxicity, metabolism & residue	$14,520	$72,600	$87,120		

	Description	Current Fee	New Fee (Year 1 @ 75%)	New Fee (Year 2 @ 90%)	Current Performance Standard	New Performance Standard
	depletion studies to establish a temporary ADI, MRL & a withdrawal period for one dosage form, dosage & route in 1 species.					
4	For food animals, toxicity, metabolism & residue depletion studies to establish an ADI with a SF of 1,000, a MRL & a withdrawal period for one dosage form, dosage & route in 1 species.	$21,790	$108,950	$130,740		
5	For food animals, toxicity, metabolism & residue depletion studies to establish an ADI with a SF of <1,000, a MRL & a withdrawal period for one dosage form, dosage & route in 1 species.	$29,050	$145,250	$174,300		
6	For food animals (once a ADI and a SF of #1,000 has been established), metabolism studies to establish a withdrawal period for one dosage form, dosage & route in an additional species.	$7,260	$36,300	$43,560		
7	Chemistry & manufacturing for 1 dosage form with a noncompendial medicinal ingredient. (A medicinal ingredient previously evaluated within the last 3 years, to which reference is made is not required to be re-evaluated. In that case, the fee for item 8 would apply.)	$4,840	$24,200	$29,040		
8	Chemistry & manufacturing for 1 dosage form with a compendial medicinal ingredient.	$2,420	$12,100	$14,520		
	Notifiable Change or Protocol Review				90 calendar days to review application	No change
1	Information & material to support an application for a Notifiable change.	$1,300	$6,500	$7,800		

	Description	Current Fee	New Fee (Year 1 @ 75%)	New Fee (Year 2 @ 90%)	Current Performance Standard	New Performance Standard
2	Request for review of scientific information outside of a regular drug submission (i.e. review of a proposed trial protocol).	$1,300	$6,500	$7,800		
	Experimental Studies Certificate				60 calendar days to review application	No change
1	Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a non-food-producing animal.	$960	$960	$960		
2	Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that for a previously authorized experimental studies certificate for a drug to be administered to a non-food-producing animal.	$480	$480	$480		
3	Information and material to support the issuance of an experimental studies certificate for a drug to be administered to a food-producing animal.	$2,900	$2,900	$2,900		
4	Information and material to support the issuance of an experimental studies certificate whose protocol is the same as that for a previously authorized experimental studies certificate for a drug to be administered to a food-producing animal.	$480	$480	$480		
	Emergency Drug Sale				2 calendar days to review application	No change
1	Information and material to support the sale of a drug to be used in the emergency treatment of a non-food-producing animal.	$50	$50	$50		
2	Information and material to support the sale of a drug to be	$100	$100	$100		

	Description	Current Fee	New Fee (Year 1 @ 75%)	New Fee (Year 2 @ 90%)	Current Performance Standard	New Performance Standard
	used in the emergency treatment of a food-producing animal.					

Veterinary Drug Right to Sell

Name of Fee	Description	Current Fee	New Fee	Current Performance Standard	New Performance Standard
Vet Right To Sell	Annual fee for the right to maintain a veterinary drug on the Canadian market	$50 - $250	$627	120 calendar days to update Drug Product Database following receipt of a complete Annual Notification	20 calendar days to update Drug Product Database following receipt of a complete Annual Notification

ANNEX C: INTERNATIONAL ANALYSIS

Health Canada's fees are determined based on the cost of providing service to industry. Irrespective of this, in developing its proposal Health Canada reviewed several international regulatory regimes, which charge fees for their therapeutic product regulatory activities. Health Canada focused its analysis on three international regulators: Australia's Therapeutic Goods Administration (TGA) / Australia's Pesticides and Veterinary Medicines Authority (APVMA), the European Medicines Agency (EMA) and, the United States Food and Drug Administration (US FDA). Overall, the regulatory frameworks may be generally aligned (type of products regulated, classifications, etc.), but there are significant differences in execution, what types of products or services have fees, how fees are structured or calculated as well as size of the regulators. These differences make it very difficult to compare services, processes and methods when it comes to fees and the application of cost recovery.

Each regulator has its own unique processes and guidelines for regulating drugs and medical devices, and approach to implementing fees. Examples of some of these differences as they compare to us are:

- The US FDA bases their fees on revenue targets rather than a fee-for-service model determined by direct costs, and often includes significant additional commitments that are not related to review performance.
- The EMA is not directly involved in the regulation of medical devices, leaving that oversight to Notified Bodies, which charge a range of fees across member countries. They also leave the regulation of establishments and sites to the member countries, focussing only on products.
- The APVMA submission review fee although is lower than that proposed by Health Canada, they split these costs between the application review (40%) and an annual product levy based on product sales. Their policy intent is to ensure that the application fee to assess and register new and innovative products is not a disincentive to bringing them into the market, particularly for small businesses, niche products and chemical products that have a low value of sales.

Although comparisons between the regulatory bodies are challenging to decipher, the fees proposed by Health Canada in many cases are lower than their international counterparts and the department is committed to maintaining competitive services and fees. See summary tables below on estimated fees across jurisdictions.

Medical Device Fees

Legend **$ = < $75,000** **$$= $75,001 - $200,000** **$$$ = $200,001 +**	**Health Canada (proposed revised fees)**	***Australia's Therapeutic Goods Administration***	***European Medicines Agency***	***United States Food and Drug Administration***
Medical Device Class IV Application	$	$	n/a	$$$
Medical Device Right to Sell Fee	$	$	n/a	$
Medical Device Establishment Licence	$	$	n/a	$

Example: In 2017 a company paid $1,132 to the TGA and $10,303 (CDN) to the US FDA for a Medical Device Right to Sell. Health Canada is proposing $500.

Human Drug Fee

Legend **$ = < $75,000** **$$= $75,001 - $200,000** **$$$ = $200,001 +**	**Health Canada (proposed revised fees)**	***Australia's Therapeutic Goods Administration***	***European Medicines Agency***	***United States Food and Drug Administration***
Human Prescription New Active Substance Drug Submission (1 indication, 2 strengths)	$$$	$$$	$$$	$$$
Human Generic Drug Submission	$	$$	$$$	$$
Drug Right to Sell Fee (human prescription, non-biologic)	$	$	$$	$$
Drug Establishment Licence (human prescription drug, sterile fabricator)	$	$	n/a	$$$

Example: In 2017 a company paid $89,080 (CDN) to the TGA, $269,794 (CDN) to the EMA, $88,298 (CDN) to the US FDA for a Human Generic Drug Submission. Health Canada is proposing $70,383.

Table 3: Veterinary Drug Fees

Legend **$ = < $75,000** **$$= $75,001 - $200,000** **$$$ = $200,001 +**	**Health Canada (proposed revised fees)**	***Australia Pesticides and Veterinary Medicines Authority***	***European Medicines Agency***	***United States Food and Drug Administration***
Veterinary New Drug Submission – Companion Animal	$$	$	$$	$$
Veterinary New Drug Submission – Food Producing Animal	$$	$$	$$	$$
Veterinary Drug Right to Sell Fee (per product)	$	$	$	$
Veterinary Drug Establishment Licence (non-sterile fabricator)	$	$	$	$$

Example: In 2017 a company paid $92,753 (CDN) to the APVMA, $315,125 (CDN) to the EMA and $438,375 (CDN) to the US FDA for a Veterinary New Drug Submission – Food Producing Animal. Health Canada is proposing $273,500[6].

[6] This includes: Efficacy & safety data (intended species) for one route, dosage form & indication in 1 species. For antiparasitic, several indications in 1 food species at $15,980; for food animals, toxicity, metabolism & residue depletion studies to establish an ADI with a SF of <1,000, a MRL & a withdrawal period for one dosage form, dosage & route in 1 species at $29,050; Chemistry & manufacturing for non-compendial medicinal ingredient. (A medicinal ingredient previously evaluated within the last 3 years, to which reference is made is not required to be reevaluated) at $4,840; and Chemistry & manufacturing for one strength of 1 dosage form at $4,840.