Health Canada Santé Canada

Health Products and Food Branch

Cost Recovery Framework:

Official Notice of Fee Proposal for Human Drugs and Medical Devices

July 2007

Canada

Your Health & Safety — Our Priority

Contents

Executive Summary

This document constitutes official notice by the Health Products and Food Branch (HPFB) of Health Canada of its fee and service standards proposal for human drugs and medical devices.

HPFB is actively engaged in a thorough review of all its activities with a view to modernizing the Canadian regulatory system and strengthening its position as an internationally recognized leader. The Cost Recovery Initiative – a financial cornerstone of this review – is designed to contribute to the funding of resources for maintaining and enhancing performance associated with regulatory services.

In accordance with both its own and Treasury Board's (TB) guidelines for delivering quality service, HPFB first released the *Cost Recovery Framework: Consultation Document* in April 2007 and invited online comments. It also conducted an extensive series of stakeholder meetings with representatives from industry, patient communities, health professionals and consumer groups. The valuable feedback garnered from these sources provided the basis for this official notice.

Responding to requests from sector representatives, HPFB agreed to delay cost recovery for Natural Health Products until the current submissions backlog is eliminated, and the full costs of compliance are better identified.

The activity-based "full" costing approach is explained, as are measurable and internationally comparable service standards.

Upon completion of the Official Notice and associated Complaints Process, a formal User Fee Proposal will be tabled in both Houses of Parliament in Fall 2007.

Along with a review of the branch's core funding, the Cost Recovery Initiative will ensure stable funding for the regulatory process and contribute to our ultimate priority – the health and safety of Canadians.

Additions and Revisions

Highlights of new or revised information presented in this document are presented in point form below (document section references are in parentheses). More details can be found in the sections that follow.

- This document relates only to fees and service standards for drugs and medical devices. (1.)
- HPFB intends to delay the implementation of fees for natural health products until the submission backlog is cleared. The current expectation is about two years, and further stakeholder consultation on the matter will be obtained. (1.1.)
- A separate consultation report describing stakeholder input is available: *Cost Recovery Framework: Stakeholder Consultation Report*. (2.)
- A separate report describing HPFB's cost development approach will be available in: *Cost Recovery Framework: Cost Development in Support of HPFB User Fees*. (3.2.1.)
- The approach for setting service standards is clarified (3.2.2.)
- A change in the interpretation of the application of penalties under the *User Fees Act* is proposed: service standards missed beyond 10% of target times will be subject to penalties (3.2.2.)
- In addition to legislated reporting requirements associated with the *User Fees Act*, HPFB will provide regular reports on post-market surveillance and compliance activities and on management efforts to improve pre-market review processes. (3.2.2, 4.2.6, 5.)
- Two separate consultation reports on international fee and service standard comparisons will be available: *Cost Recovery Framework: International Comparison of Fees and Service Standards for Medical Devices* and *Cost Recovery Framework: International Comparison of Fees and Service Standards for Drugs*. (3.3.)
- Fee mitigation conditions and validation requirements are proposed. (3.4.)
- Additional information on the approach to revising fees using an automatic annual fee adjustment is provided. (3.5.)
- The rationale for submission evaluation fees and service standards, including the use of flat fees, is explained. (4.2.1.)
- A new fee is proposed for submissions switching from a prescription to non-prescription drug. (4.2.2.)
- Certain biologic submission evaluation fees have been revised. (4.2.3.)
- A new fee is proposed for drug submission evaluations supported only by published data. (4.2.4.)
- A proposal is offered for streamlining Medical Devices Class III/IV Significant Change Amendments. (4.2.5.)
- The rationale for the Cost Sharing Ratio in setting fees for Establishment Licensing Activities has been expanded. (4.3.1.)

- The proposed fee structure for Medical Device Establishment Licences is explained. (4.3.1.)
- HPFB will pursue a fee for an annual Good Clinical Practices Licence, but first seeks to obtain more consultation feedback on the fee level and application from affected stakeholders. (4.3.2.)
- More information is provided on Authority to Sell fees and service standards. (4.4.)
- Service delivery process improvement activities currently under consideration are described. (5.)
- The proposed dual site licensing regulatory amendment is explained, which would alleviate the exporting challenges arising from the coming into force of the Natural Health Products Regulations. (5.3.)
- Additional information on total costs and revenues by fee type is provided. (6.1.)
- Next steps and the complaints process are described. (7.)
- Revised tables identifying all proposed fees, service standards and fee mitigation conditions and validation are provided. (Annex 1)

1. Introduction

Health Canada's Health Products and Food Branch is actively engaged in the Blueprint for Renewal ("the Blueprint"), a thorough review of all of the Branch's activities with a view to modernizing the Canadian regulatory system and strengthening its position as an internationally recognized leader. The Cost Recovery Initiative – a financial cornerstone of the Blueprint – is designed to contribute to the funding of resources required to maintain and enhance performance associated with regulatory services. This Initiative will, along with a review of the branch's core funding, serve to ensure stable funding for the regulatory process and contribute to our ultimate priority – the health and safety of Canadians.

Despite its important role within the Blueprint, the Cost Recovery Framework will not at this time incorporate any of the new ideas or concepts currently being assessed in conjunction with other Blueprint initiatives. Costs and fees are built around activities that reflect current services rather than how they will evolve under the Blueprint umbrella.

This document constitutes official notice by the Health Products and Food Branch (HPFB) of Health Canada of its fee proposal for human drugs and medical devices. Having received comments from stakeholders, HPFB has incorporated their feedback into this document and revised the proposals made in the March, 2007 *Cost Recovery Framework: Consultation Document.*

Included in this document are specific fees and service standards related to regulatory responsibilities in the area of market approval, facility inspections and investigations, and post-market monitoring of marketed products for pharmaceuticals, biologics, and medical devices. Cost recovery options for veterinary drug evaluations and natural health products will follow at a later date.

1.1. Cost Recovery and Natural Health Products

During the course of the consultation process, many stakeholders commented on the potential adverse impacts of the proposed cost recovery framework. In particular, those in the Natural Health Products (NHP) sector were concerned about the additional burden fees would cause, given the existing compliance costs they are experiencing as a result of the recently introduced NHP regulations.

They argued that a delay could allow the sector to focus their efforts on compliance initiatives and implement them in the most expeditious and effective manner. Some stakeholders also noted that under current circumstances, predictable service standards may not be assured. This situation could jeopardize both future revenues and funding support for natural health product regulatory activities.

HPFB agreed that it would be inappropriate to implement fees before the current submissions backlog is cleared. Accordingly, HPFB intends to delay the implementation of fees for NHPs until the submissions backlog is cleared—in about two years—and further stakeholder consultation on the matter obtained. HPFB has consequently excluded NHPs from any discussions in this proposal.

A detailed implementation schedule will be developed and published to ensure appropriate consultation with interested and affected parties.

2. The Consultation Process

Health Canada is committed to consultations as a means of delivering quality service, to improve knowledge and to better understand health issues. In the case of user fees, consultations are required under the *User Fees Act*. Treasury Board also includes this requirement in its *Policy on Service Standards for External Fees*.

In early April, 2007 HPFB released the *Cost Recovery Framework: Consultation Document* and invited online comments until May 15 through a series of questions and a Business Impact Test (BIT). Concurrently, it held meetings with a wide variety of stakeholders from industry, patient communities, health professionals and consumer groups.

Valuable stakeholder feedback has been received, and this document reflects many of the suggestions proposed by stakeholders. Details on specific issues addressed and comments made during the consultation process can be found in a separate report entitled *Cost Recovery Framework: Stakeholder Consultation Report*.

3. Cost Recovery

3.1. Background

Cost recovery refers to the act of charging a fee for a government service to those who receive the service or benefit from it. Health Canada began implementing fee regulations in 1995 to recover a portion of the costs of drug regulatory activities. By 2000, fees were also in place for medical devices regulatory activities. In March 2004, the *User Fees Act* became law, requiring that any changes to fees charged for regulatory activities offered by Health Canada include:

- Stakeholder consultation;
- A comparison of proposed fees and service standards with those in other countries where a comparison is relevant;
- The establishment of an independent advisory panel to report recommendations for resolving complaints on the proposed user fees; and
- A Ministerial tabling of the user fee proposal in each House of Parliament.

The *User Fees Act* links service standards with fees charged and collected by a program or department. Under the Act, Health Canada is required to report annually on costs, fee revenue and performance against service standards as well as feedback received from stakeholders. When performance subject to the *User Fees Act* in a particular fiscal year does not meet the established standards by a percentage greater than ten per cent, the corresponding fee will be reduced proportionately by up to 50% of the fee level for the next fiscal year.

Several factors have contributed to the need to update fees charged for regulated services HPFB provides. When fees were originally implemented, not all activities were considered for user fees. Additionally, the volume and complexity of activities have expanded since that time. Additional time and enhanced vigilance is now required to provide regulatory services. Standards for manufacturing site and facilities inspections have evolved to include the implementation of more stringent global standards in today's environment. Marketed health product monitoring demands have increased dramatically, and more sophisticated adverse reaction reporting, risk identification and benefit/risk assessments are being employed. Additionally, the Auditor General (OAG) has highlighted the need to improve program management and delivery, and performance reporting, and to ensure that the Branch recovers a reasonable portion of its costs for regulatory programs from fees.

The current fees were calculated based on the costs required to operate the program at the time they were implemented. This has led to cost recovery levels that are considerably less than actual program costs. A forecast for the next three years indicates that, compared to 1995 levels, the difference between costs incurred to fee revenue generated from regulated services will grow well beyond $100M by 2008/09. With no offsetting funding from other sources, HPFB will face a potentially large funding gap at that time. Given that fees have not increased since originally implemented, updating the cost recovery program for regulatory services will contribute a greater share to overall Branch funds and reduce the impending funding shortfall.

3.2. Approach

3.2.1. Cost Development and Fee Setting

In the March 2007 Consultation Document, HPFB outlined an integrated approach to cost recovery. It first involved identifying what activities undertaken by the Branch should be eligible for cost recovery. Services and activities had to be legitimate and necessary functions of the Government of Canada, consistent with government commitments and resulting in a direct benefit to an external party. Consideration was also given as to whether the fee would result in a reasonable benefit to Health Canada that would outweigh the cost of administering it. This approach identified a number of activities eligible for cost recovery. Activities excluded from cost recovery included: blood establishment licensing, emergency response activities, public health programs, new knowledge development activities, patent review activities, litigation, special access programs including donor semen special access programs, and clinical trial applications.

HPFB has used an activity-based "full" costing approach, consistent with Treasury Board guidelines. This included the costs of resources required to provide each service or activity needed by the individual or group directly responsible for the program, as well as the costs of resources from other groups or organizations that support the program. These latter activities also include a portion of corporate management and governance activities, such as human resources, legal services, program evaluation, finance, and audit.

For drugs and medical devices products, HPFB has developed unit costs for each service utilizing internal tracking data and information from the financial system for the fiscal year 2005/06 and adjusted them to 2007/08 levels using a blended cost increase factor devised from publicly available cost indices to reflect labour and non-labour components of cost recoverable activities.

To achieve an appropriate balance of funding sources, not all costs were fully recovered. Costs to be recovered for four specific fee categories were determined, and then a cost sharing formula based on the relative level of benefit received by the fee paying industry in relation to the public benefit derived from the activity was applied. Fee categories used and associated cost sharing ratios (percentage of full costs for which fees should be derived) included:

- Submission evaluations (75%);
- Establishment licensing (100%);
- Authority to sell (50%); and
- Master files and certificates (100%).

During the stakeholder consultation process, several parties requested additional information on the approach used to establish costs. To ensure that all parties have access to more detailed information on the cost recovery approach, a separate document entitled *Cost Recovery Framework: Cost Development In Support of HPFB User Fees* has been created. It includes the information provided at the bi-lateral sessions and a further description to clarify how "full costs" were developed and how cost sharing ratios were used to establish the proposed fee levels.

3.2.2. Setting Service Standards

A service standard is a statement of the expectations or requirements established in consultation with paying and non-paying stakeholders for a regulatory activity at a particular rating level. In its *Policy on Service Standards for External Fees,* Treasury Board notes that service standards must be:

- Measurable and internationally comparable;
- Relevant at the level of the paying stakeholder;
- Consulted on with both paying and non-paying stakeholders; and
- Reported to Parliament annually, with a summary of stakeholder feedback from consultation.

For each fee, HPFB has identified service standards that reflect the level of service that can be expected. Service standards already apply today for fee-related activities for drugs and medical devices. HPFB intends to utilize the same service standard approach for the fees proposed in this proceeding.

HPFB believes that the proposed service standards are consistent with the Branch's capacity to deliver within the level of resources that the proposed fees and associated appropriations funding will provide.

With the wide variety of standards currently reported, HPFB believes that there is considerable value in ensuring that a simple and representative service standard measure is associated with each fee. For example, an internal standard exists for the screening of drug submissions (45 days) and review (60 to 300 days depending on the type of submission). During the screening activity, applications are inspected to ensure all material is complete and of suitable high quality to be reviewed. The review segment is a more critical activity, involving an evaluation of the safety, efficacy and quality of data and establishing the basis for assessing the potential benefits and risks of the product. The review activity is the *key aspect of the service being supplied and the one that effectively triggers the fee*. This distinction and rationale is proposed to be the means for establishing what service standards should be used in respect of accountability measures under the *User Fees Act*. HPFB believes that such an approach is simple and effective, and consistent with Treasury Board's Policy described above.

HPFB does not believe that the service standards reported for purposes of the *User Fees Act* should be the only measure of its regulatory effectiveness. HPFB has a responsibility to demonstrate that the highest levels of service are provided to fee payers as well as other Canadians who support the regulatory program through tax dollar contributions.

Associated with each service standard are single or multiple delivery time targets, depending upon the fee element. The service standard for Medical Devices Class III licence application (all medical devices including in-vitro diagnostic) is based on the time taken to complete the review. The single service standard target time in this case is 60 days. Some fee elements, though, are characterized by a number of different subtypes, and in those cases, multiple targets are used. For example, for most New Active Substance submissions the service standard is 300 days, but for a Priority Review New Active Substance submission, the service standard is 180 days. Performance for this fee element will be calculated by assessing service delivery results against each of these target times. The accumulated difference on an annual average must be within 10% of the target to meet the service standard.

In the original March 2007 Consultation Document, HPFB indicated that the proposed service standard was one in which time targets would be met within 10%, and that performance would be determined by calculating the average time spent for all activities in a specific fee category, relative to the corresponding target times for that category. If the performance was more than 110% of target, then the service standard would be missed. The original proposal also included the interpretation that the *User Fees Act* provides a 10% leeway in meeting service standards. HPFB understood this to mean that if the actual performance in a given fiscal year is more than 121% of the target for that fee category, penalties would apply for the amount in excess. This interpretation created some concern from stakeholders. By allowing a 10% leeway on top of its defined service standards, these groups felt that HPFB's interpretation would lessen the accountability requirement of the *User Fees Act*.

HPFB recognizes that its interpretation of how service standards would relate to the 10% leeway provided in the *User Fees Act* could create some confusion among stakeholders. However, having recently cleared the drugs review backlog, there is considerable risk for HPFB to meet the proposed standards given its relatively short experience in that capacity.

In the interests of fairness to those who feel uncomfortable with the definition originally proposed, and in the sprit of providing greater accountability in fulfilling its regulatory obligations, HPFB proposes that the *User Fees Act* penalty be applied when the average performance is beyond 110% of the associated time target(s).

A number of stakeholders expressed concern during this proceeding that the service standards identified in this proposal did not include all standards currently reported by the Branch. HPFB wants to clearly state that it intends to continue to publish the service standards it currently uses, and to report them on a regular basis, at minimum annually. HPFB also intends to report on additional measures and activities that go beyond what it has traditionally made available to the public. Over the next two years, it will conduct an internal assessment to evaluate and introduce additional measures that would extend its information and performance reporting capabilities beyond the performance standards proposed in this proceeding, and those it currently publishes.

HPFB is committed to service improvements and will use these additional measures as a means to facilitate an on-going dialogue with stakeholders on mechanisms to improve service delivery and regulatory performance.

3.3. International Comparison

In the March 2007 Consultation Document, HPFB provided a comparison of its proposal with the fees and service standards available in the United States, United Kingdom, European Union and Australia. HPFB felt that these countries had the most comparable regulatory frameworks and that its proposed fees and service standards are internationally comparable.

In arriving at that conclusion, HPFB undertook a thorough and extensive review of jurisdictions that it believes to be relevant for meaningful comparison. It has also attempted to compare product differences in a reasonable and responsible manner. Fully understanding the products to be compared and the circumstances in which jurisdictions around the world undertake some form of regulatory oversight of health products presents challenges to obtaining reasonable and relevant comparisons. The organization structure, cost recovery approaches, and legislated mandates vary widely among regulatory jurisdictions. Despite differences, HPFB believes that the four jurisdictions chosen provide sufficient levels of information and similarity to the Canadian framework to allow reasonable comparisons to be made.

With regard to the analysis provided in the consultation document, stakeholders noted that not all product lines were included, and that the countries used were not necessarily appropriate for comparison across all product lines. It was also noted that the analysis did not reflect the regulation that applied to natural health products in many countries throughout the world.

In the interests of increased transparency on this subject, HPFB has provided additional information on fee and service standard comparisons in two separate reports entitled: *Cost Recovery Framework: International Comparison of Fees and Service Standards for Medical Devices*, and *Cost Recovery Framework: International Comparison of Fees and Service Standards for Drugs.*

3.4. Fee Mitigation

3.4.1. Approach

In the initial Consultation Document, the principles and criteria for fee mitigation were presented and stakeholders were invited to identify appropriate mechanisms and circumstances appropriate for mitigation. The Business Impact Test (BIT) also asked companies to provide information regarding historical and anticipated fee mitigation.

The HPFB approach to fee mitigation focuses on facilitating the availability of health products to help the people of Canada maintain and improve their health. A consistent approach across product lines has been taken, and all processes will be objective, transparent and based on evidence. Proposed mechanisms will be as simple and affordable as appropriate.

Although there was general support for maintaining existing fee mitigation mechanisms, some mechanisms are being adjusted and additional new measures are being introduced to respond to reported impacts and stakeholder suggestions. A fee mitigation proposal has been put together for each fee group, and is detailed in Annex 1. HPFB is interested in receiving additional comments from stakeholders on these proposals in the coming weeks.

With regard to fees to be paid when mitigation measures are applied, HPFB recognizes the expense to companies as well as to Health Canada of preparing, processing and depositing payments. Accordingly, payment of individual fees under $50 will be waived, provided appropriate supporting documentation is provided to support the request. Under mitigation conditions, such fee levels may be obtained when fee caps based on low volume of sales in Canada are applied. For example, a cap limited to 1.5 % of wholesale sales in Canada applies to Authority to Sell Drugs Fees. In this case, the fee for a product with Canadian sales of $2,000 would be $30, a charge that would be waived under the condition proposed above.

3.4.2. Measures

Many different circumstances were identified by stakeholders as potentially requiring mitigation. Most of these circumstances address one of the two criteria required for consideration of mitigation: directly related to an undue financial burden (and therefore as a potential barrier to access), or directly to access. Those that are not associated with one of these criteria are not considered appropriate for mitigation. In general, there were four categories of circumstances deemed appropriate for mitigation: products with low volume of sales, organizations not selling for profit, start-up companies, and humanitarian / public health situations. Rare, orphan and paediatric products will be mitigated when they qualify under the low volume of sales criteria.

To address financial viability impacts, all fees will be capped for products and companies with low volume of sales. This will address those situations where fees may represent a disproportionate percentage of sales or profit, usually more applicable to small businesses. HPFB believes this approach is equitable and should provide benefits for a large number of affected businesses.

Organizations not selling for profit, such as hospitals, public health institutions, academic institutions, charities and non-profit organizations, will be exempt from all fees. This will remove fees as a potential burden to allow these organizations to continue to participate in the health care system.

Companies that have been in business for less than one full year will be granted a 12 month extension (a fee delay) for payment of any fee. This delay will provide start-up companies with the opportunity to secure required funding to cover this regulatory expense, but still require payment of the full fee; however these companies may also apply for mitigation based on low volume of sales if appropriate.

In circumstances where a government department has requested a submission or product for humanitarian or public health reasons, the product evaluation and annual licensing fees will be waived. This addresses government policy, and the *User Fees Act*, which do not consider fees charged between government departments to be appropriate in this manner.

Submissions made under Canada's Access to Medicines Regime will not be required to pay fees initially. If the product is granted authorization under s. 21.04 of the *Patent Act* by the Canadian Intellectual Property Office (Industry Canada) and is issued a Compulsory Licence, the fees will be waived. If however, the product does not receive a Compulsory Licence then the fees will become payable upon expiry of the innovator's patent, potentially subject to additional fee mitigation measures based on volume of sales. Although currently addressed through individual remission orders, this regulatory proposal will simplify the elimination of fees as a potential burden to making these products available as required.

Additionally, there will be a fee to consider a request for fee mitigation on the grounds of low volume of anticipated sales for a drug submission or medical device application review fee. The fee will be based on the cost of reviewing supporting information for the mitigation, and is deemed appropriate given the potential magnitude of the waived amount. For all drug submissions, the fee will be $500 and $50 for Class III and IV medical devices.

The detailed mitigation proposals are included in Annex 1 – Proposed Fees, Service Standards and Fee Mitigation Conditions.

3.4.3. Validation

Validation requirements will be appropriate to the mechanism and magnitude of the fee mitigation, although the Minister will always have the right to request audited sales records to verify any mitigation granted.

Since the revised fee for submission and application evaluation fees is based on anticipated sales, upon final validation, the final fee payable may be adjusted higher or lower based on actual sales.

All product evaluation and establishment licensing fee mitigation measures will be validated with company financial statements. For annual authority to sell fees, companies will be required to submit a certified statement of sales (by product) to support their request for fee mitigation. Evidence supporting additional criteria (i.e., non-profit status, request from Public Health Agency of Canada) will also be required.

3.4.4. Master Files and Certificates

Activities related to the filing, processing and issuance of Master Files and Export Certificates are not regulatory in nature. They are voluntary services provided by HPFB that provide significant private benefit and no significant benefit to Canadians. Fees are based on recovering 100% of the associated costs. No fee mitigation is proposed.

3.5. Revising Fees in the Future

In the March 2007 Consultation Document, HPFB proposed to apply an annual adjustment factor to fees to reflect changes in costs applicable to fee-based services, without conducting a major fee review. Currently automatic fee adjustments do not apply to HPFB fees, but the Federal Administration Act (Section 19.2) provides the authority to do so.

It was proposed that the annual adjustment factor be derived by applying current annual public service wage-based cost increase factors and the current annual core consumer price index in a blended manner to each fee, each factor weighted by the overall ratio of HPFB's labour (83%) and non-labour (17%) costs respectively. This approach was used to derive 2007-8 cost estimates from 2005-6 costs – the base year for cost studies undertaken to develop fees. This represented an annual increase of about 2.5% per year.

In consultation, some parties questioned whether such an annual adjustment by itself is appropriate, especially if it is not directly linked to a review of activities or costs. There was a concern that an automatic fee adjustment would not be an accurate reflection of costs and that it might simply allow program costs to escalate without appropriate efforts to improve processes. Others noted that industry is required to account for efficiencies on a regular basis and does not have the luxury of building in automatic increases.

HPFB continues to believe that an annual adjustment factor will lessen the potential adverse impacts of any fee increases required to keep pace with escalating costs of changing regulation over time. In the future, it will also deploy techniques and approaches to improve program efficiencies, since the imposition of penalties for missed service standards is a significant incentive to ensure costs are controlled, and resources effectively managed. HPFB has also indicated that every three years it will review costs associated with its fees and propose new or amended fees to reflect that review. At that time, all fees subjected to annual adjustment factors will be adjusted in accordance with detailed cost estimates developed at that time.

Accordingly, HPFB intends to implement an automatic fee adjustment approach based on the method described above. The adjustment factor would be derived from the Bank of Canada's annual core CPI and an annual average of Wage Increases in Collective Agreements (WIC - Annual Index) and the Annual Wage Adjustments in Major Settlements (AAWA) as published by Statistics Canada. Data for the latest period would be incorporated into a five year running average. The cost increase factor would be applied at the beginning of each new fiscal year following the first year of implementation of the current proposed fees. The following year the adjustment would be made again, incorporating the newly available index data.

4. Clarifying Proposed Fees and Service Standards

4.1. Overview

In Annex 1 to this document, a revised table of fees and service standards is provided. This Annex describes each fee group, allowing for a comparison between existing fees (if applicable), full unit cost as determined through the activity-based costing data, and proposed fees. Target times are also indicated and form the basis of the proposed service standards. It also summarizes mitigation approaches applicable to each fee category.

Important changes have been made to the revised Annex 1, notably in the exclusion of fees and service standards for NH products. Other changes to the original Annex are discussed within this document under the applicable sections that follow.

4.2. Submission Evaluation Fees and Service Standards

4.2.1. Rationale

Submission and Application Evaluation Fees cover pharmaceutical and biologic drug evaluations as well as medical device product reviews. These fees are charged to evaluate documentation submitted by a manufacturer to demonstrate the safety, efficacy and quality of a product for specific conditions of use.

The proposed fee structure for drug submission evaluations continues to be based on submission components required for review purposes. However, instead of levying fees for separate components that are accumulated to determine a final fee, the proposed fee structure establishes an aggregate level or flat fee to reflect the main submission activities associated with the reviews.

Product approval provides companies with the opportunity to distribute their product in Canada and to obtain the related revenues and associated profits. It also provides competitive leverage, measured as the opportunity to increase market share by competing against similar products available in the marketplace. There is also public benefit to having new or greater varieties of drug products available in Canada. Canadians can benefit from the confidence that safe products are available for their use and that they have access to what may be the most advanced drugs offered.

The medical device fee structure is also based on flat fees. The risk based classification for the various classes of medical devices is maintained between classes and within classes as well (e.g. medical device containing human or animal tissue, near patient). New licence applications will be charged a single fee, rather than a total charge based on accumulated components.

The flat fee structure applied to drugs and medical devices will simplify the fee as it applied to the application process, align it to respective costs and provide an increased level of cost certainty for fee payers.

4.2.2. Switching from a Prescription to a Non-Prescription Drug

During consultation discussions, HPFB was asked to consider eliminating or reducing the fee for drug submissions related to switching a drug product from prescription to non-prescription status. The concern expressed was that a lack of patent protection following such a switch eliminates the private benefit associated with marketing these products. Additionally, it was argued, there is a lower level of effort required to review non prescription drug submissions, and fees should reflect this.

HPFB believes that the issue of patent protection for switched products is beyond the scope of this proceeding. It also does not support the view that private benefit for product sponsors is significantly reduced by such a switch.

Although there was no specific fee for switch submissions in the original proposal, the intent is to charge a relevant submission component fee. This approach will accommodate the various types of switch submissions and varying levels of effort associated with review. Upon further investigation of switch review activities, HPFB has determined that a specific fee for the review of switch submissions for the same condition of use (exact same product) is necessary as the level of effort for these types of submissions is different from the existing fee components in the previous fee structure. At a cost sharing ratio of 75% consistent with other fees in the submission evaluation category, the fee for this latter type of switch is proposed to be $41,280.

4.2.3. Biologics

During consultations, concern was expressed by certain stakeholders in the Biologics sector that the significant difference between the proposed fee for a Biologic submission and that of a Therapeutic submission had not been adequately substantiated.

In response to the stakeholder concerns, HPFB undertook to revisit the cost development approach used for establishing all Biologics submission review fees.

This analysis revealed that only a small number of Biologic Comparative Chemistry and Manufacturing submissions are handled annually. Since the population size used to develop 2005-6 base year costs for this category may not have been sufficiently large enough to substantiate the fee differential for applications of this type, HPFB believes that in the interest of fairness to affected parties, the Biologics fee for Comparative Chemistry and Manufacturing submission evaluation should be set lower. HPFB has concluded that the Biologics fee for Comparative Chemistry and Manufacturing submission evaluations should be revised to $50,000 by using additional level of effort data attributable to comparable pharmaceuticals activity. This is a reduction from the original fee proposal of $122,180.

HPFB also reviewed data for other submission evaluation activities and is confident that the costs derived were consistent with tracking results from the other years, with one exception - the fee for Chemistry and Manufacturing, Labelling. HPFB has investigated this activity and reduced the fee to $76,000 from the $81,190 originally proposed.

4.2.4. Submissions Supported Only by Published Data

Under the existing fee structure in the Drug Evaluation Fees Regulations, a fee of $2,200 applies to drug submissions supported only by published clinical data or other published references. During consultation, it became clear that there was no appropriate fee in the proposal for these types of submissions. An analysis of costing information was subsequently conducted to identify a fee for published references in support of the drug review process.

HPFB has identified a full unit cost of $22,670 for this activity. Under the 75% cost sharing arrangement for submission evaluations, this would produce a fee of $17,000.

Similar to the application of other service standards elsewhere in this framework, this submission component will have multiple delivery time targets. The target time for this regulatory service will depend on the type of submission component the references support: 300 days for clinical only and chemistry & manufacturing (C&M) /clinical reviews, 180 days for Comparative/C&M evaluations, and 60 days for submissions requiring only labelling changes.

4.2.5. Significant Change Amendments - Medical Devices Class III/IV

During the consultation it was observed that the proposed fees for Class III and IV significant change amendments were significant and could possibly have been introduced with more reasonable impacts under a component-based fee schedule.

After further analysis, HPFB believes that there is a comparable level of effort, within each risk category (Class III and IV), required to assess most significant change amendments. An exception exists for changes to manufacturing which requires less effort for assessments.

HPFB is streamlining its proposal so that three fees replace the original ten proposed. All fees have a 75% cost sharing ratio applied. The fees for Medical Devices, Class III/IV significant changes in manufacturing are to be set at $1,270. All other Class III significant change amendments will be charged at $4,730. All other Class IV significant change amendments will be charged at $5,390. The proposed service standards will remain unchanged.

4.2.6. Service Standards

Throughout the consultation period, stakeholders offered considerable comment and suggestions on how proposed service standards for submission evaluations could be changed to provide greater accountability.

Some industry stakeholders noted the possibility that a Notice of Deficiency (NOD) or a Notice of Non-compliance (NON) could be issued just prior to the expiration of a service standard target, allowing HPFB to meet its target but delaying considerably the outcome of the product review. It was suggested that including additional service standards beyond a basic time metric for reviews e.g. standards for meetings, training, quality of review, shelf time vs. processing time, more formalized “stop clock” provisions, etc. would help to ensure that sufficient and efficient progress was being made in undertaking each application review.

Representatives from consumer and patient groups commented on the possibility that safety considerations could be short-changed due to pressures on reviewers to meet service standard target dates. Suggestions to alleviate these concerns included a third party assessment of safety matters in the review process and greater overall transparency through the issuance of clinical trial safety reports, a rationale for missed service standards, and reports on the results of safety inspections.

While HPFB agrees with the fundamental concerns raised by stakeholder on these matters, it believes that having such a variety of service standards subject to fee reduction penalties under the *User Fees Act* may have negative consequences on the quality of the regulatory programs offered. For purposes of the *User Fees Act*, it intends to adopt the service standards proposed for this category of fees. However, HPFB also intends to make more information available to stakeholders on work undertaken to improve its regulatory submission evaluation processes and will commit to publicly reporting on efforts undertaken by each Directorate to improve both its measurable and non-measurable submission evaluation processes and performance.

4.3. Establishment Licensing Fees and Service Standards

4.3.1. Rationale

Establishment Licensing Fees cover compliance activities such as site and facility inspections to evaluate the suitability of establishments to engage in production, distribution or testing of drug and medical device products.

In its original stakeholder consultation document, HPFB proposed a 100% cost sharing ratio on the grounds that an Establishment Licence provides a world recognized standard (good manufacturing practices – GMP) of excellence that allows industries to produce or distribute products not only in Canada, but for other countries around the world. The competitive advantage to industry in obtaining this licence is deemed to be significant.

During the consultation session, certain stakeholders questioned the cost sharing applied to the Establishment Licensing fees category, noting that the fees should be reduced to reflect the public safety benefits of the activities they cover. HPFB continues to believe that the cost sharing ratio is appropriate because there is a substantial benefit that industry enjoys with this service.

Therefore HPFB will maintain the cost sharing ratio for fees in the establishment licensing category at 100% as originally proposed.

During consultation, a number of stakeholders commented on subjects relating to the fee structure: the suitability of using a flat fee regardless of the level of effort, or risk; whether fees should be based upon level of compliance; whether consideration should be given to a different fee for renewal. The following comments are offered in support of the current proposal.

A risk-based approach would not necessarily reflect the potential amount of effort required to conduct an inspection or issue a licence. While some products may not appear to pose substantial risk on application, incorrect use of that product can create any range of associated risks that may require a significant amount of work to investigate and rectify. It is very difficult in advance to identify for what products and to what extent a response is required.

With respect to the suggestion that a (lower) renewal fee be applied, there is no evidence to indicate that issuing a licence renewal takes less effort or time than issuing a licence for a first time applicant. All first time applicants require a Good Manufacturing Products (GMP) inspection prior to the issuance of a Drug Establishment Licence (DEL), however many renewal applicants also require a GMP inspection. The amount of time or effort required for both is comparable and the associated process is the same whether it is for an initial licence or renewal.

Regarding Medical Device Establishment Licensing (MDEL) fees, some stakeholders suggested that a component based fee structure modeled on the DELs would be more appropriate than the proposed flat fee that would apply regardless of the function of the site. However, MDELs are issued to a company for all qualifying sites, and there is no GMP requirement associated with the issuance of a licence. Therefore a component based fee model is not appropriate for these fees. The cost difference for issuing a fabricator licence and an importer licence is minimal.

In this proposal no changes are proposed to the existing fee structure.

4.3.2. Good Clinical Practices Annual Licence (for Clinical Trial Sites)

In the March 2007 consultation document, HPFB proposed an annual licensing fee for clinical trial sites. Such action will require a change to the existing regulations which currently excludes an establishment licensing requirement for activities relating to clinical trial drugs.

HPFB is concerned about whether sufficient feedback from stakeholders on this fee has been obtained, particularly from those in the academic and health care environments who may not have recognized the impact on their activities. In the coming weeks, HPFB intends to conduct further consultations with those most likely to be affected by this action.

4.3.3. Service Standards

During the course of consultation, a number of stakeholders commented on the appropriateness of service standards for these fees. Some indicated that additional qualitative standards needed to be employed and that the DEL service standard of 250 days to issue a licence was too long. With respect to this latter concern, a suggestion was made to adopt a staggered licensing approach to reduce the bottleneck that occurred with all applications being submitted at the same time.

Internationally, although they all charge annual fees for the licensing of facilities, the United States, Australia and the European Union do not have service standards related to establishment licensing activities.

HPFB recognizes the concerns expressed by stakeholders and has taken steps to examine means to improve service in the Establishment Licensing area. Some of these initiatives are described in Section 5 of this Report. Until such time as some of these initiatives can be implemented, and the potential for reducing or modifying service standards fully tested, the proposed service standards are appropriate and realistic.

4.4. Authority to Sell Fees and Service Standards

4.4.1. Rationale

In addition to covering the cost of processing and administering annual licensing, the Authority to Sell (ATS) fees support programs and activities associated with post-market surveillance and adverse reaction monitoring (approximately 43% of the fee), compliance and enforcement activities (37%), new policy development related to the implementation of a product life cycle regulatory approach (3%), and information technology development (17%).

HPFB has proposed that a single flat fee apply for all products within the Drugs or Medical Devices fee groups. The authority to sell fee affects virtually all fee paying constituents and spreads the costs of post-market work across the largest number of licence holders.

During consultations, some stakeholders questioned the 50% cost-sharing ratio applied to the ATS fees, suggesting that the ratio should be reduced given the significant public safety benefits of the activities they cover.

HPFB believes that the benefits that industry receives from activities relating to these fees are balanced with the public benefits. The authority to sell a product in Canada provides companies with revenues and profits and competitive advantages. Canadians as a whole also benefit from efforts undertaken to ensure that post-market adverse events and compliance and enforcement initiatives are acted upon quickly and effectively, or that greater efficiency is developed and applied to the manner in which the regulatory function is carried on.

A fee level set at 50% of full costs, as originally proposed, has been used for determining fee levels for ATS fees.

4.4.2. Service Standards

HPFB has proposed that service standards of 120 days and 20 days to process an annual license renewal apply to drugs and medical devices applications respectively.

In establishing service standards for its fees, HPFB has been mindful of the premise that service standards should be measurable and relevant at the level of the paying stakeholder.

HPFB believes that standards such as the time required to assess and communicate safety risks should not be designated as service standards for purposes of the *User Fees Act*. It is understood that missed service standards relating to pre-market product submission processing time may adversely affect the paying industry and they should benefit through fee reductions when that happens. However, it is not reasonable to suggest that they should benefit from reduced fees if service standards relating to post-market safety activities are missed. It is the Canadian public that is principally impacted by the resulting reduction in program funding, not that the fee paying group.

The United States does not have service standards related to post-market surveillance activities, even though they charge annual product licensing fees. The United Kingdom and Australia do have some service standards related to the processing of adverse event reports and investigations.

With respect to ATS fees, the best way to show accountability for safety matters is by being more transparent in reporting results of related efforts. In the course of the consultations, HPFB proposed the issuance of an annual report which was viewed favourably by stakeholders. Such a report would be provided in addition to the reporting of service standards required for *User Fees Act* purposes, and would highlight activities undertaken in support of its regulatory mandate and a review of internal performance and key initiatives undertaken in the post-market area.

4.5. Master Files, Certificates and Service Standards

Master Files and Certifications Fees include fees for facilities/compliance activities relating to the processing, reviewing and administration of Drug Master Files, Certificates of Pharmaceutical Compliance (formerly Drug Export Certificates), and Medical Device Certificates. These services are provided at the request of industry. Even if the related fees cover activities that are not regulatory in nature and thus, not subject to the *User Fees Act*, HPFB intends to report the costing and performance information in the same manner as other fees.

Industry is the primary beneficiary of the activities related to the issuance of certificates and establishment of master files. For certificates, there is no significant advantage to the general Canadian public since companies use these certificates to support foreign submissions. Master files are primarily established at the request of a manufacturer to facilitate the approval of drugs submissions by allowing Health Canada access to supporting information required in the evaluation process without compromising its proprietary nature. Effectively, the master file increases the number of producers a manufacture of non-medicinal or medicinal ingredients can sell its product to. The market advantage gained, both internationally and nationally, is important enough for industry to request these services and fully defray the related costs.

Service standards for this category have been set to recognize that the time to process a submission is the primary measurable outcome of these activities. Target times vary according to the complexity of the activity – they are either 10 days or 30 days.

5. Service Delivery

5.1. Transparency and Accountability

During the consultation process, considerable emphasis was place on the need for greater transparency and accountability. Stakeholders also noted a requirement to increase efforts in overall process and service improvements.

HPFB agrees with these comments and will pursue enhanced reporting on post-market surveillance and compliance activities, on safety responsiveness and other related matters, as well as on management efforts to improve pre-market review processes.

It is anticipated that this will stimulate feedback from stakeholders and result in positive benefits to HPFB. This is consistent with the Branch commitment within the Blueprint for Renewal "to promote a more open and transparent regulatory system in which the involvement of patients, consumers, health professionals and researchers contributes to better overall quality of regulatory decision making."

5.2. Process Improvements

Stakeholders identified several suggestions for service delivery and process improvements during consultations. HPFB is committed to service improvements and offers the following activities towards achieving this goal.

With respect to compliance activities, HPFB undertakes site and facility inspections to evaluate the suitability of establishments to engage in production, distribution or testing of drug and medical device products. A number of issues associated with reaching enhanced levels of service delivery have been identified and efforts have been initiated to address how to make process improvements to the Establishment Licensing system.

Plans are being developed to improve service delivery in a number of areas, notably to:

- Reduce backlogs in the issuance of establishment licences for Drug and Medical devices;
- Modernize and improve the transparency of results from the internal tracking and review reporting systems;
- Define a process for initiating the establishment licensing renewal process earlier in the year;
- Implement a screening process for incoming applications; and
- Work more closely with industry on educational initiatives designed to improve the quality of submissions received.

In the context of the consultations, stakeholders identified a number of specific suggestions for improvements regarding product submission evaluations. Many of these are currently being assessed. Of particular concern was the need for harmonization and international recognition, with the potential for cost avoidance. Other stakeholders requested an assurance that if a submission is not picked up for review until late in the time target (i.e., experiences a long shelf life), that the quality of the review is not jeopardized through the issuance of an interim decision (NON/NOD, AI Letter), or that an unsafe product is recommended for approval in order to meet the time target.

With regard to submission evaluation improvements, a variety of initiatives is underway to improve processes and include consideration of those concerns described above. Key activities include:

- Increasing the focus on peer/ panel review processes, training, project plans, and risk management of submissions;
- Integrating IT electronic support (e-review) to the processes of product submission and regulatory review;
- Completing an analysis of NOD/NON issuance with the goal of improving review practices and educating review bureaus on consistent approaches to identifying and remedying related issues;
- Increasing the number of on-going Bi-Lateral Meeting and discussion forums with stakeholders;
- Using External Resources for Review to better manage workload fluctuations; and
- Establishing a Quality Management System within the Biologics and Genetic Therapies Directorate with a goal to achieve ISO 9001 compliance, and ICH 17025 (laboratory specific) compliance in the near future.

Other submission evaluation improvement initiatives within the Therapeutic Product Directorate comprise the following:

- Establishing Good Review Practices: review standards (such as standard operating procedures and templates) and related initiatives (such as reviewer manuals and training programs) designed to ensure the timeliness, predictability, consistency, and high quality of reviews and review reports;
- Updating and developing guidance documents to help stakeholders navigate regulatory requirements and to ensure that these requirements are transparent; and
- Implementing a Memorandum of Understanding (MOU) with TGA of Australia to eliminate the necessity for duplicating quality management system (QMS) audits currently required when manufacturers export their medical devices to each others' jurisdictions.

With respect to post-market activities surrounding Authority to Sell fees, the following activities are underway to improve service delivery and internal processes:

- Implementation of performance standards for post-market surveillance, compliance and enforcement activities, e.g. adverse reaction report coding and data entry and inspection completion benchmarks;
- Implementation of a new adverse reaction report processing system improvements to the MedEffect website;
- Improved processes for monitoring regulatory advertising complaints;
- Increased resource staffing and training for post-market surveillance activities, and the use of external resources for assistance in workload fluctuation management; and
- Improved time tracking, cost control and reporting measures.

From another perspective but related to service improvement, several stakeholders suggested introducing incentives such as a reduced fee for those sponsors who provide exemplary submissions. HPFB sees merit in further investigating these suggestions and will consider a compliance-related factor in the context of the next fee review process.

5.3. Proposed Dual Site Licensing Amendment

Over the past two years, Health Canada has been working on a proposed dual site licensing regulatory amendment to alleviate the exporting challenges arising from the coming into force of the *Natural Health Products Regulations* (NHPR). It would allow, on a voluntary basis, natural health product (NHP) companies to hold a Drug Establishment Licence pursuant to the *Food and Drug Regulations*, in addition to a Site Licence. In order to export their products to countries that classify them as drugs and to benefit from export opportunities provided through existing international mutual recognition agreements, it is necessary for companies to hold a DEL and obtain the accompanying Health Canada issued export certificates.

A key feature of the proposed regulatory amendment is that this is not a new or mandatory fee which is to be applied to all NHP companies. Discussions regarding the broader issue of fees related to the licensing of natural health products will continue. However, NHP companies will be able to voluntarily apply to hold a DEL (and pay the associated fees for a DEL) in addition to the required NHP Site Licence to regain the ability to export their products. The amendment would have no effect on those NHP companies and other stakeholders who have expressed the view that Health Canada should not engage in cost recovery with respect to the licensing of NHPs until performance targets at the Natural Health Products Directorate have been reached.

6. Annual Reporting and Costs and Revenues

6.1. Annual Reporting Requirements

The *User Fees Act* requires that the Minister annually report to Parliament on how revenues are derived from all user fees, on relevant related costs, dispute management activities, consultations, service standards and results achieved. For all user fees, Treasury Board policy also requires that service standards performance and related consultations be reported.

The report is to be tabled by the Minister responsible before the House of Commons and/or the Senate on or before December 31 following the end of the fiscal year to which the information relates.

For the last two fiscal years, HPFB has been reporting this type information, including revenues from fees together with associated costs and service standards in the Health Canada Departmental Performance Report (DPR) and intends to continue this effort in future years.

6.2. Estimated Costs and Revenues

During the consultation process, a number of stakeholders requested additional information on costs and revenues attributable to the fee proposals. Details on how the costs were developed are provided in a separate document entitled *Cost Recovery Framework: Cost Development in Support of HPFB User Fees*.

Information on costs and related revenues for cost recoverable activities were originally developed for the Branch and included natural health products. With a delay in the implementation of fees for natural health products and in response to stakeholder requests for more information in this area, HPFB has developed Branch costs and revenues by product line.

HPFB estimates that in 2007-8 it will cost about $154M to support all cost recoverable activities undertaken within the four Directorates affected by the proposed fee increase: Therapeutic Products, Biologic & Genetic Therapies, Health Products and Food Branch Inspectorate and Marketed Health Products. Recoverable costs for that year represented the foundation for fees developed in this proposal.

Mitigation is estimated to be about $17.9M in 2008-9. Revenues to be obtained that year from the fees proposed are forecasted to be approximately $92M after mitigation. This should represent about 60% of total recoverable costs.

Estimates of full recoverable costs and revenues by fee type are shown below.

Table 1 – HPFB Total Regulatory Activity Costs and Revenues (2007-8 $M)

Fee Category	Projected Recoverable Costs* (2007-08)		Projected Revenue (2008-9)		% of recoverable costs	% of total revenue from cost recovery
Authority to Sell	**$49.6**		**$24.8**		**50.0%**	**22.6%**
Pharmaceuticals	$27.8		$13.9			
Biologics	$9.1		$4.6			
Drugs subtotal		$36.9		$18.5		
Medical Devices	$12.7		$6.3			
Submission/Application Review	**$75.8**		**$56.8**		**75.0%**	**51.7%**
Pharmaceuticals	$41.9		$31.4			
Biologics	$24.3		$18.2			
Drugs subtotal		$66.2		$49.6		
Medical Devices	$9.6		$7.2			
Establishment/Site Licencing	**$27.8**		**$27.8**		**100.0%**	**25.3%**
Pharmaceuticals	$13.4		$13.4			
Biologics	$0.5		$0.5			
Drugs subtotal		$13.9		$13.9		
Medical Devices	$13.9		$13.9			
Master File/Certificates	**$0.5**		**$0.5**		**100.0%**	**0.5%**
Pharmaceuticals	$0.5		$0.5			
Biologics	$0.0		$0.0			
Medical Devices	$0.0		$0.0			
Grand Total	**$153.7**		**$110.0**		**71.5%**	**100.0%**
Less Estimated Mitigation			**$17.9**			
Total Revenue After Mitigation			**$92.0**		**59.9%**	
Fee Category Costs and Revenues After Mitigation						
Pharmaceuticals	$83.7		$50.2		60.0%	54.5%
Biologics	$33.9		$20.3		60.0%	22.1%
Drugs subtotal		$117.6		$70.5	60.0%	76.6%
Medical Devices	$36.2		$21.5		59.5%	23.4%

**Full Costs - includes program, branch and corporate costs for recoverable activities*

7. Next Steps

7.1. Complaints Process

With the issuance of this document, a 14-day notice period for additional comment begins. If parties disagree with the proposed fees and/or service standards, and the way in which HPFB proposes to manage them, stakeholders can file a formal complaint no later than 30 days from the end of the notice period.

Upon receiving a complaint, HPFB will first attempt to resolve the matter through discussion with the complainant and the provision of additional information if appropriate.

If the parties cannot agree at this stage in the matter, an Independent Advisory Panel will be formed. Both the regulator and the complainant will select one member to sit on the Panel and the two members will then select a third.

The Panel will review relevant facts, identify points of agreement and disagreement, meet with the appropriate representative(s) to discuss and review the complaint and provide non-binding advice and recommendations to Health Canada on how the dispute might be resolved. The timeframe for completing this is legislated to take no more than 70 days after the end of the notice period.

Health Canada ultimately decides on the matter, including the awarding of costs. The Panel may recommend that costs be awarded or that the complainant bear costs if the matter is deemed frivolous.

Any questions, inquiries or complaints can be channelled to the Cost Recovery Initiative by:

Telephone: (613) 946-0107

Email : CRI_IRC_consultations@hc-sc.gc.ca

Additional information is available on the Cost Recovery Initiative website at www.healthcanada.gc.ca/hpfb_costrecovery.

7.2. Implementation Schedule

The following table indicates scheduled dates for remaining activities associated with the implementation of the Cost Recovery Framework and the approval process for this proposal.

Activity	Timeframe
Complaint process (per User Fees Act)	Summer 2007
Table Fee Proposal with Parliament (per User Fees Act requirement)	Fall 2007
Regulatory Proposal published in Canada Gazette I for consultation	Winter 2007
Implementation of revised fees for drugs and medical devices	Spring 2008
Note: Revised fees will not be implemented for Natural Health products until elimination of the current submission backlog and consultation on revised proposed fees and service standards	

7.3. Parliamentary Review

As prescribed in the *User Fees Act,* a fee proposal must be tabled in each House of Parliament. The proposal will include a description of the service, licence or authorization related to the fee, the reason for the fee, internationally comparable performance standards and actual performance levels, revenue estimates for three years and identification of associated costs. The proposal will also include a description of how any complaints were addressed through the independent advisory panel process.

Each House will assign this proposal to the appropriate Committee to review. A Committee has 20 sitting days to review the proposal and to submit a report containing a recommendation to the House of Commons or Senate; if no report is submitted, the Committee is deemed to have approved the proposal.

Health Canada will be submitting a user fee proposal for drug regulatory fees, and a separate proposal for medical device regulatory fees, to Parliament in early fall 2007.

7.4. Regulatory Changes

Revised fee regulations will be drafted and published in the *Canada Gazette* for comment after Parliament has reviewed the user fee proposal. The current target publication time is the winter of 2008.

Annex 1:
Proposed Fees, Service Standards, and Fee Mitigation Measures

The associated target time(s) for each respective fee category will be met within 10%.

Target Time is the average time expected for completion of the target activity described, expressed in calendar days.

Target time shown may be representative of additional target times defined for specific applications related to that fee element e.g. drug submissions for unmet medical needs have shorter time targets than the identified category time target of 300 days - i.e., priority=180 days & NOC/c submissions=200 days as time targets.

More detailed description of specific fee elements, target times and processes can be found in existing product group Guidance documents available from the Health Canada web site.

Fee mitigation conditions are summarized at the end of each fee category table.

Table 1: Submission and Application Fees						
Fee Category	**Fee Description**	**Current Fee**	**Full Unit Cost**	**Proposed Fee**	**Time Target Description**	**Time Target**
Drug Submission Fees						
New Active Substance	Pharmaceuticals	$143,800 - $264,900 (component-based)	$404,635	$303,480	Days to review a submission	300
	Biologics	$143,800 - $264,900 (component-based)	$522,347	$391,770	Days to review a submission	300
Clinical/Chemistry & Manufacturing	Pharmaceuticals	$68,200 - $212,000 (component-based)	$204,945	$153,710	Days to review a submission	300
	Biologics	$68,200 - $212,000 (component-based)	$210,200	$157,650	Days to review a submission	300
Clinical Only	Pharmaceuticals	$52,900 - $105,800 (component-based)	$95,641	$71,740	Days to review a submission	300
	Biologics	$52,900 - $105,800 (component-based)	$132,426	$99,320	Days to review a submission	300
Comparative/Chemistry & Manufacturing	Pharmaceuticals	$44,000 - $76,500 (component-based)	$57,805	$43,360	Days to review a submission	180
	Biologics	$44,000 - $76,500 (component-based)	$66,667	$50,000	Days to review a submission	180
Chemistry & Manufacturing/Labelling	Pharmaceuticals	$15,300 - $30,600 (component-based)	$27,326	$20,500	Days to review a submission	180
	Biologics	$15,300 - $30,600 (component-based)	$101,333	$76,000	Days to review a submission	180

Table 1: Submission and Application Fees						
Fee Category	**Fee Description**	**Current Fee**	**Full Unit Cost**	**Proposed Fee**	**Time Target Description**	**Time Target**
Drug Submission Fees						
Published Data Only	Pharmaceuticals	$2,200	$22,670	$17,000	Days to review a submission	300/180/60
Rx to OTC Switch	Pharmaceuticals - Review of information and material to support the removal of a drug from Schedule F of the Food and Drug regulations (same condition of use)	$17,200	$55,040	$41,280	Days to review a submission	180
Labelling Only	Pharmaceuticals	$0 - $2,200 (component-based)	$3,679	$2,760	Days to review a submission	60
	Biologics	$0 - $2,200 (component-based)	$3,679	$2,760	Days to review a submission	60
Notifiable Change Evaluation (includes C&M only, excludes Labelling NCs)	Pharmaceuticals	N/A	$5,570	$4,180	Days to review a submission	90
	Biologics	N/A	$6,306	$4,730	Days to review a submission	90
Administrative Submission		$250	$285	$285	Days to process a submission	45
DIN Submission Fees						
DIN A	Submission review fee Supporting data determines application of appropriate drug submission fee	$720 - $52,900		See Drug Submission Evaluation fees for Clin/C&M; Clin only; Comp/ C&M; C&M/ Labelling; labelling only	Days to review a submission	210
DIN B (Biologics)	Submission review fee for a biologic Supporting data determines application of appropriate drug submission fee	$720 - $52,900		See Biologics Submission Evaluation fees for Clin/C&M; Clin only; Comp/ C&M; C&M/ Labelling; Labelling only	Days to review a submission	210

Table 1: Submission and Application Fees						
Fee Category	**Fee Description**	**Current Fee**	**Full Unit Cost**	**Proposed Fee**	**Time Target Description**	**Time Target**
Drug Submission Fees						
DIN Submission Fees (cont)						
DIN D	Fee for review of an application for a disinfectant	$720	$5,092	$3,820	Days to review a submission	180
DIN A, DIN D, DIN F	Fee for verifying application's adherence to labelling standards or monographs	$310	$2,037	$1,530	Days to review a submission	45

Drug Submission Review Mitigation		
	Proposed	**Current**
Mechanisms	• $500 fee to consider reduction based on low volume of anticipated sales • Fee capped at 10% of anticipated gross sales for first two years on market (once marketed / notified) • Exempt: submissions made for humanitarian / public health reasons (e.g., products sold to DND, PHAC), submissions made by non-profit organizations, submissions granted a Compulsory License under Canada's Access to Medicines Regime • Delay: delay of 12 months for first year of company's operation; submissions made under "Canada's Access to Medicines Regime " but not granted a Compulsory Licence do not pay until patent expires in Canada	• $1000 fee to consider request • Fee capped at 10% of anticipated revenue from sales of the drug in Canada for the first three years on the market
Validation Measures	• To support request: information to support anticipated revenue, including market / product analysis, price and forecasted volume • After three years on market: certified company financial statements (by product); letter from DND or PHAC or proof of non-profit/charity status; readjust fee based on actual sales if necessary	• Information to support request must detail current market situation, including data from similar products, analysis of target population and product demand, average price/volume, comparison to similar products on Canadian market • Validated (after three years) with audited sales records

Table 1: Submission and Application Fees						
Fee Category	**Fee Description**	**Current Fee**	**Full Unit Cost**	**Proposed Fee**	**Time Target Description**	**Time Target**
Medical Devices Submission Fees						
Medical Devices Licence Application Evaluation Fees						
Class II - Licence Application		$200	$459	$350	Days to review an application	15
Class III - Licence Application		$1980 (component-based)	$6,726	$5,050	Days to review an application	60
Class III - Licence Application (Near Patient In Vitro Diagnostic Devices)		$2420 (component-based)	$11,456	$8,600	Days to review an application	60
Class IV - Licence Application		$10,170 - $11,870 (component-based)	$15,660	$11,750	Days to review an application	75
Class IV - Licence Application (Devices that contain human / animal tissue)		$12,790 - $14,490 (component-based)	$14,609	$10,960	Days to review an application	75
Class IV - Licence Application (Near Patient In Vitro Diagnostic Devices)		$12,580 - $14,280 (component-based)	$26,694	$20,030	Days to review an application	75

Table 1: Submission and Application Fees						
Fee Category	**Fee Description**	**Current Fee**	**Full Unit Cost**	**Proposed Fee**	**Time Target Description**	**Time Target**
Medical Devices Submission Fees						
Medical Devices Significant Change Amendments (Class III & IV) Fees						
Changes in Manufacturing	Changes in manufacturing processes, facility, equipment of quality control procedures	Class III $140 - $310 (component-based)	$1,682	$1,270	Days to review an application	60
		Class IV $140 - $1670 (component-based)	$1,682	$1,270	Days to review an application	75
All Other Significant Changes	Changes in device's design, including its performance characteristics, principles of operation, energy source, software or accessories Changes to sourcing or processing of materials of human or animal origin Changes in a generic material type Changes in formulation; Modifications to family device licences; Labelling changes in response to changing requirements (e.g., indication of use, contraindications)	Class III $140 - $2,200 (component-based)	$6,307	$4,730	Days to review an application	60
		Class IV $140 - $14,490 (component-based)	$7,187	$5,390	Days to review an application	75
Medical Device Application Review Mitigation						
	Proposed			**Current**		
Mechanisms	• $50 fee to consider mitigation for Class III or IV medical device applications based on low volume of anticipated sales; waive for Class II • Fee capped at 5% of anticipated gross sales for first two years on market • Fee delay of 12 months for first year of company's operation • Exempt: applications for humanitarian / public health reasons (e.g., products sold to DND, PHAC), applications by non-profit organizations			• Reduced fee of $50 for Class II devices if original fee payable is more than 5% of anticipated first two years' gross revenue • Fee capped at 5% of anticipated first two years' gross revenue for Class III and IV devices		
Validation Measures	• After two years on market: certified company financial statements (by product); letter from DND or PHAC or proof of non-profit/charity status; readjust fee based on actual sales if necessary			• Validated (after two years) with certified statement of sales / certified sales records; readjust fee based on actual sales if necessary		

Table 2: Establishment Licensing Fees						
Fee Category	**Fee Description**	**Current Fee**	**Full Unit Cost**	**Proposed Fee**	**Time Target Description**	**Time Target**
Drug Establishment Licensing Fees						
NOTE: The Target Time to issue a licence is 250 for any combination of the activities below.					Days to issue a licence	250
Good Manufacturing Practices Component						
A. Fabrication						
Basic Fee		$6,000	$15,450	$15,450		
Each Additional Category		$1,500	$3,862	$3,870		
Dosage from Classes						
2 classes		$3,000	$7,725	$7,730		
3 classes		$6,000	$15,450	$15,450		
4 classes		$7,500	$19,312	$19,320		
5 classes		$9,000	$23,175	$23,180		
6 classes		$10,500	$27,037	$27,040		
Each additional class		$600	$1,545	$1,550		
Sterile dosage forms		$3,000	$7,725	$7,730		
B. Packaging/Labelling						
Basic Fee		$4,000	$10,300	$10,300		
Each Additional Category		$1,000	$2,575	$2,580		
Dosage from Classes						
2 classes		$2,000	$5,150	$5,150		
3 or more classes		$3,000	$7,725	$7,730		
C. Importation/Distribution						
Basic Fee		$2,500	$6,437	$6,440		
Each Additional Category		$625	$1,609	$1,610		
Dosage from Classes						
2 classes		$1,250	$3,219	$3,220		
3 classes		$2,500	$6,437	$6,440		
Each fabricator		$600	$1,545	$1,550		

Table 2: Establishment Licensing Fees						
Fee Category	**Fee Description**	**Current Fee**	**Full Unit Cost**	**Proposed Fee**	**Time Target Description**	**Time Target**
Drug Establishment Licensing Fees						
NOTE: The Target Time to issue a licence is 250 for any combination of the activities below.					Days to issue a licence	250
Good Manufacturing Practices Component						
C. Importation/Distribution (cont)						
Each additional dosage from class for each fabricator		$300	$772	$780		
D. Distribution and Wholesaling						
Distribution and Wholesaling Fee		$1,500	$3,862	$3,870		
E. Testing						
Testing Fee		$1,000	$2,575	$2,580		
Drug Analysis Component						
Vaccines	Product laboratory analysis activities based on the risks Associated with various broad product types	$10,000	$25,750	$25,750		
Schedule D Drugs which are not vaccines or whole blood and its components		$4,000	$10,300	$10,300		
Drugs for Human Use listed in Schedule F to the Food and Drug Regulations or controlled drugs or narcotics		$3,000	$7,725	$7,730		
Drugs with DINs or GPS (not included in any other item)		$1,500	$3,862	$3,870		
Controlled Substances Component						
Controlled Substance Inspection	The Controlled Substances component applies to inspection of security and record keeping of firms licensed to handle controlled drugs or narcotics	$1,750	$4,507	$4,510		

Table 2: Establishment Licensing Fees						
Fee Category	**Fee Description**	**Current Fee**	**Full Unit Cost**	**Proposed Fee**	**Service Standard Description**	**Service Standard**
Drug Establishment Licensing Mitigation						
	Proposed			**Current**		
Mechanisms	• Fee capped at 1% gross revenue by company, for the previous fiscal year • Fee delay of 12 months for first year of company's operation • Exempt public hospitals, public health institutions, charities (i.e., non-profit organizations)			• Fee capped at 1.5% of gross revenue from sales, testing and packaging/labelling of drugs • Exemption for public hospitals and public health institutions		
Validation Measures	• Certified company financial statements; proof of non-profit/charity status			• Financial records submitted at time of request / self-attestation		
Good Clinical Practice Annual Licensing Fees						
Good Clinical Practice Licence	Annual license fee for clinical trial sites	n/a	$650	$650	Days to issue a licence	30
Good Clinical Practice Establishment Licensing Mitigation						
	Proposed			**Current**		
Mechanisms	• Exempt: applications made by non-profit organizations			n/a		
Validation Measures	• Proof of non-profit status			n/a		
Medical Device Establishment Licensing Fees						
Medical Devices Establishment Licence		$2,120	$8,467	$8,470	Days to issue a licence	120
Medical Device Establishment Licensing Mitigation						
	Proposed			**Current**		
Mechanisms	• Reduced fee of 1% gross revenue by company, for the previous fiscal year • Fee delay of 12 months for first year of company's operation • Exempt Non-profit organizations (including public hospitals, public health institutions)			• Fee capped at 1.0% of the establishment's annual gross revenue from the previous fiscal year		
Validation Measures	• Certified company financial statements; proof of non-profit/charity status			• Validated by Certification form		

Table 3: Master Files/Certifications						
Fee Category	**Fee Description**	**Current Fee**	**Full Unit Cost**	**Proposed Fee**	**Time Target Description**	**Time Target**
Master File Fees						
Drug Master File Registration	Registration of a reference source that contains proprietary information about specific processes or components used in the manufacturing, processing and packaging of a drug	$350	$395	$400	Days to process a submission	30
Letter of Access Fee	A letter written by the DMF Holder permitting Health Canada to reference information in the DMF on behalf of a sponsor	$50	$176	$180	Days to process a submission	30
Bi-annual Updates	Bi-annual updates required to keep DMF open and active	n/a	$176	$180	Days to process a submission	30
Certification Fees						
Certificate of Pharmaceutical Product	A certificate establishing the product listed and the GMP status of the fabricator of the product; in the format recommended by the WHO	$50/$25	$53	$60	Days to process a submission	10
Certificate of Medical Device	A certificate establishing the status of the medical device listed and the GMP status of the fabricator of the product; in the format recommended by the WHO	$50	$53	$60	Days to process a submission	10

Table 4: Authority to Sell Fees						
Fee Category	**Fee Description**	**Current Fee**	**Full Unit Cost**	**Proposed Fee**	**Time Target Description**	**Time Target**
Drug Authority to Sell Fees						
Drugs (DINs)	Annual fee for the right to maintain a drug product on the Canadian market	Targeted substances, Narcotic, Schedules D, F, G=$1000 Other drugs=$500 Other disinfectants =$250 Disinf Med Device= $500	$2,021	$1,020	Days to process annual notification	120
Drug Authority to Sell Mitigation						
	Proposed			**Current**		
Mechanisms	• Fee capped at 1.5% of product wholesale sales • Fee delay of 12 months for first year of company's operation • Exempt: products made available for humanitarian / public health reasons (e.g., products sold to DND, PHAC), or by non-profit organizations, or products under the "Drugs for Africa" legislation (only until patent expires)			• Reduced fee of $50 if annual wholesale sales of the drug in Canada are less than $20,000		
Validation Measures	• Certified statement of sales (by product); letter from DND or PHAC or proof of non-profit/charity status			• Certification at time of request		
Medical Device Authority to Sell Fees						
Medical Devices	Annual fee for the right to maintain a medical device on the Canadian market	$50 (revenues <$20,000) - $100	$641	$330	Days to process annual notification	20
Medical Device Authority to Sell Mitigation						
	Proposed			**Current**		
Mechanisms	• Fee capped at 1.5% of product wholesale sales • Fee delay of 12 months for first year of company's operation • Exempt: products made available for humanitarian / public health reasons (e.g., products sold to DND, PHAC), or by non-profit organizations			• Reduced fee of $50 if annual gross revenue less than $20,000 • Fee cap for total annual fee payable by any company is 1.5% of the total gross revenue in Canada		
Validation Measures	• Certified statement of sales (by product); letter from DND or PHAC or proof of non-profit/charity status			• Validated by Certification form		