Health Canada’s Proposal to Parliament for User Fees and Service Standards for Human Drugs and Medical Devices Programs

April, 2010
Executive Summary

Health Canada is the federal authority responsible for regulating the safety, efficacy and quality of human drugs and medical devices, as mandated by the *Food and Drugs Act*. Pursuant to this legislation, all such products must undergo medical and scientific evaluations to assess their benefits and risks before they are made available to Canadians. Health Canada also administers post-market surveillance activities, such as inspections and assessments of adverse reactions. In undertaking these regulatory activities, Health Canada is committed to protecting and promoting the health and safety of Canadians.

In 1995, Health Canada moved to charge fees to industry for certain of these activities, such as the evaluation of new drugs. Canada is not alone in this approach. In fact, all comparable international regulators charge fees for these services, as industry derives significant private benefits from them. Such fees support part of the cost of Health Canada’s independent scientific assessment and are paid whether a human drug or a medical device is approved for sale or not.

Since the introduction of user fees, the cost for Health Canada to perform these activities has increased. Health Canada’s expert evaluators and inspectors are required, for example, to deal with increased volume of data in submissions, along with more complex science and an increase in available surveillance information.

While the costs have increased, user fees remained the same. This means that the revenues from user fees now cover approximately 23% of the cost of service provision; whereas revenues represented approximately 50% of the costs of the services when fees were first established. Canadian taxpayers have borne a much larger share of the cost of these services, and Health Canada faces ongoing challenges in performing its regulatory function.

Canada is alone amongst international health product regulators in not updating user fees since their implementation. Revenues from fees cover 50% of the cost of these services in the United States, 60-70% in Europe, and 100% in the United Kingdom, and Australia.

In 2004, Health Canada undertook a significant project to update its cost recovery framework, consistent with the requirements of the *User Fees Act*. Consultations have been undertaken with industry, health professionals, patients and consumers, and independent review panels have addressed complaints that have been raised. The culmination of this work has resulted in this User Fees Proposal (Proposal), which sets out an updated fee structure based on the costs of the services and the proposed private sector cost share.
The Proposal only applies to human drugs and medical devices. It does not apply to natural health products, for which there is no current cost recovery regime. Provisions are also included to reduce fees for companies with product lines with low revenue streams, recognizing that there may be some applicants who have difficulty paying these fees.

Under this Proposal, annual revenues for Health Canada would increase to $112.4 million from the approximate $47 million it receives currently, and would restore the original cost sharing ratio of approximately 50% when fees were first introduced. This funding would contribute to a stable funding platform to provide important regulatory services for Canadians. Health Canada will use the resources to support the work of its expert staff to assess the safety, efficacy and quality of human drugs and medical devices, to conduct post-market surveillance of these products, and to inspect and assess the compliance of human drug and medical device establishments. It will assist Health Canada to conduct scientific assessments within internationally comparable time targets, thus enabling Canadians to have timely access to safe, effective and high quality drugs and medical devices.

The revenues from this cost recovery proposal would complement recent public investments in the regulation of drugs and medical devices. Budget 2008 funding in the Food and Consumer Safety Action Plan supported, for example, the establishment of a Border Integrity Strategy, and enhanced post-market surveillance of human drugs. Budget 2008 also provided funding to establish the Drug Safety and Effectiveness Network, which will support independent post-market research that will be useful to Health Canada in its regulatory functions. This Proposal also responds to the recommendations of the Auditor General in her reports of 2004 and 2006 to update user fees as part of ensuring that Health Canada’s regulatory programs related to human drugs and medical devices have sufficient resources.
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1. Introduction

For more than fifty years, Health Canada has evaluated and monitored the safety, quality and efficacy of health products available to Canadians through various activities. The Health Products and Food Branch (HPFB) of Health Canada is the federal authority that regulates human drugs and medical devices through a combination of activities outlined under the *Food and Drugs Act*. Natural health products are not considered to be human drugs for this initiative and are not included in this cost recovery proposal.

This Proposal contains information regarding the legislative authorities for conducting the fee activities described here, provides the rationale for fee increases and how those fees were developed. Appendices are included that outline the proposed fees and service standards for both human drugs and medical devices as well as recommendations of independent advisory panels and Departmental responses to them. Lastly, a number of documents are provided in a Background Binder, outlining in detail international comparisons, cost development and consultative endeavours.

**Human Drugs and Medical Devices**

In this Proposal, a wide range of products are included under the category of human drugs. Examples of these products include prescription and non-prescription pharmaceuticals, disinfectants, sanitizers with disinfectant claims and biologics and genetics therapies, such as viral and bacterial vaccines. As stated previously, natural health products are not considered to be human drugs for this initiative and are not included in this Proposal. The types and kinds of medical devices are also varied. Examples of these range from bandages and toothbrushes to artificial heart valves, hip implants, synthetic skin, medical laboratory diagnostic instruments, test kits for diagnosis and contraceptive devices.

The HPFB regulates these products via a number of activities as required under the *Food and Drugs Act*. Some of these activities include:

- Reviews of scientific information regarding the safety, efficacy and quality of human drugs and medical devices to evaluate their potential benefits and risks, pre- and post-market;
- Reviews of labelling information that the manufacturer intends to provide to health care practitioners and consumers about the product;
- Delivery of a national compliance and enforcement program, including inspections of regulated establishments (e.g. manufacturers, importers, distributors) and investigations of alleged non-compliant products or activities; and
- Issuance of licenses for regulated activities (e.g. fabrication, importation) relating to the sale of human drugs and medical devices.

**Cost Recovery in the Human Drugs and Medical Devices Programs**

In the early 1990s, Health Canada began charging fees for conducting the above regulatory activities. Fees for drugs were implemented first in a phased approach. A similar approach was introduced for medical devices in 1998. By 2000, cost recovery was established for five sets of fees for drug-related activities and three sets of fees for medical device activities. By this time, the Department had been given the authority to collect approximately $40 million in revenues for
these activities. Detailed descriptions of these fee activities are given in the “Activity Costs and Revenue Estimates” section, below.

Since the original user fees were established, many changes have occurred in the regulatory and scientific environments that have altered the way business is carried out within the programs. These changes are reflective of evolving industry, regulatory and consumer expectations; however, these new realities bring to the Department significantly higher costs of performing these activities.

In the late 1990s, the costs of delivering these services were approximately $80 million. At introduction, user fees covered approximately 50% of program costs at approximately $40 million in revenues. A comprehensive costing exercise was completed in 2006 using workload statistics for 2005. These costs were adjusted for inflation and were estimated at $153.7 million for 2007/2008. Revenues, for the same time period increased only to $43.6 million, thereby reducing the actual cost recovery ratio from the 50% in the 1990s to 28%.

Further analysis has shown that the costs of service provision are estimated at approximately $227 million for the fiscal year 2010-2011. With no indexing provisions in place, combined with the increasing costs of service delivery, it is projected that the amount of revenues that will come into the Department for these services will approximate $53 million, a cost recovery ratio of roughly 23%. As a result, Canadian tax dollars are now, and will continue to be, funding an increasingly greater portion of the costs—when compared to 1995—of regulatory services that provide a direct benefit to the fee payer. However, if user fees are modernized as described in this Proposal, it is projected that the amount of revenues received by the department will be close to $112 million. This would represent a cost sharing ratio of approximately 49%, and thus likely restore the original cost sharing ratio of the 1990s.

Cost Recovery in the Regulatory Environment
User fees are commonly charged by all levels of government for public services, including regulatory functions, where there is a private benefit derived from the service that is provided. Specifically in the area of human drugs and medical devices, all comparable international regulators charge fees for their services, and attempt to meet comparable service standards. Most countries have updated their fee levels, and many recover a larger percentage of the cost of the services than is proposed by Health Canada.

Fees are charged to cover part of the costs of conducting scientific assessments and regulatory decisions by experts at Health Canada. The fees are charged regardless of whether the product review results in an approval for sale in Canada, and the service is provided regardless of the status of the payment of the fee. The overriding principle for all Health Canada activities is the health and safety of Canadians.

2. Legislative and Policy Frameworks

The Food and Drug Regulations and the Medical Devices Regulations, under the Food and Drugs Act, provide the authority for the Minister of Health to conduct certain activities—and in particular to review submissions and applications filed under these regulations—for which the fees are being updated. The Controlled Drugs and Substances Act also provides the authority for
the Minister of Health to conduct fee-related activities. The *Financial Administration Act* allows the Department to charge fees for rights and privileges related to costs.

The *User Fees Act* (UFA), March 2004, created a legal framework within which federal entities are required to manage user fees, including the establishment and reporting of service standards. The current fees charged by the Department are not governed under the UFA, but would be if changes were to be made to the user fees. Under the UFA, a user fee is defined as a *fee, charge or levy for a product, regulatory process, permit or license, facility, or a service that is provided only by a regulating authority, that is fixed pursuant to the authority of an Act of Parliament and which results in a direct benefit or advantage to the person paying the fee.*

In November 2004, the Treasury Board Secretariat introduced a *Policy on Service Standards for External Fees*. 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 the above policy, the Treasury Board notes that service standards must be:

- Measurable;
- 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, the HPFB has identified service standards that reflect the level of service that can be expected. Currently, there are well-established service standards for human drug and medical devices fee activities. The HPFB intends to utilize the same service standard approach for the fees proposed here. If this Proposal is accepted, the current service standards will no longer be expected level of service, but will become a service commitment with recourse for underperformance, as per the UFA. The HPFB believes that these service standards are appropriate given the level of resources that the proposed fee revenues and current appropriations will provide.

In 2007, Health Canada introduced its own *Policy and Guidelines on External Charging* to guide its Branches and program areas in the development and implementation of cost recovery.

This Proposal was developed, and is being tabled, in compliance with all of the previously-cited authorities and guidelines.

### 3. Rationale for Proposal

This Proposal has been developed to:

- Update user fees regimes for the Human Drugs and Medical Devices Programs that have not been updated since their introductions in the mid- to late-1990s to reflect current costs;
- Provide a stable funding platform from which to provide regulatory service and to contribute to our priority of protecting the health and safety of Canadians;
• Respond to recommendations of the 2004 and 2006 Reports of the Auditor General regarding program sustainability.

Update User Fees from the Mid-to-Late 1990s:
Since the inception of the cost recovery regimes in the 1990s, the programs have responded to many changes in the regulatory and scientific environments. For instance, a growth in the number of health products has led to higher volumes of product submissions. Trends from the last 8-10 years show increased volume in innovator human pharmaceutical submissions from 131 in 2000 to 206 in 2008 (57% increase). For generic drug submissions, the increase is even more pronounced. The HPFB received 67 generic drug submissions in 2000, compared to 163 received in 2008 (143% increase). Forecasts for generic drug submissions suggest that by 2012, generic drug submissions will be even more common, with estimates of 250-300 per year. Submissions for biologic drugs increased from 59 in 2000 to 89 in 2008 (51% increase).
Medical device applications have also increased from 3,584 applications in 2001 to 4,973 in 2008 (39% increase).

Health Canada has also seen an increase in the number of licences issued. In 1998, 600 Drug Establishment Licences (DEL) were issued and this number has since grown to 1,075 in 2008. With respect to Medical Device Establishment Licences (MDEL), in 1998 approximately 600 MDEL were issued and in 2008 the Department issued 2,018. The volume of both DEL and MDEL applications issued is projected to increase in the coming years.

Not only have the numbers of submissions been growing, but many submissions are also increasing in scientific sophistication and complexity. Since the 1990s, submissions increasingly contain more clinical data in subpopulations such as paediatrics, geriatrics, or those with kidney or liver impairment. Additionally, recent international and national standards have also introduced new criteria that must be assessed prior to authorization. An example of this includes separate studies that look for cardiovascular effects. While these clinical studies aid in the determination of an appropriate review decision, they add further levels of complexity to the review. Additionally, medical device technology has grown rapidly with more combination products utilising devices and drugs, nanotechnology, multi-test in-vitro diagnostic devices, cardio-vascular technologies, and software driven devices.

Since the implementation of the existing cost recovery regime, there has been a substantial growth in the number of health products available in the Canadian market. In 2000, there were 10,524 licensed drugs in Canada; in 2008, there were 18,242. As of 2008, Health Canada had issued a total of 28,000 medical device licences; a significant increase from the 13,000 issued in 2000. More products on the market increase the potential for required regulatory follow-up action. Several activities may be initiated once a product has been marketed, including the surveillance of adverse reaction reports, the performance of risk identification and benefit/risk assessments, the utilization of risk communications, and the facilitation of product recalls.

The effects of these changes have placed significant pressure on the Department, as was shown in the results of a comprehensive activity-based costing approach that was developed in order to identify the full costs associated with activities subject to the current cost recovery regime.
This user fees proposal aims to update fees to reflect the increase in costs associated with providing these services, and to update the public-private cost share. As a result of this, total user fees revenues will fund approximately 50% of the costs of fee activities under the human drugs and medical devices programs, which continues to be amongst the lowest cost-sharing ratios internationally. The additional revenues generated from updated user fees will provide Health Canada with sufficient resources to perform pre- and post-market regulatory activities, including more frequent, thorough and broader-based inspection and compliance verification programs.

An increase in user fees revenues to support cost recoverable activities will complement recent injections of funding through the Food and Consumer Safety Action Plan (FCSAP) (2008). The FCSAP provided funding to address challenges in non-cost recoverable activities, but which support Health Canada’s regulatory functions. These resources enabled the creation of a border integrity program, enhanced post-market surveillance and the implementation of the Drug Safety and Effectiveness Network, which will support independent post-market research.

*Provide stable funding for the regulatory process and contribute to our ultimate priority, the health and safety of Canadians*

The potential increase in revenues, in combination with the retention of current public funding dedicated to the programs, will provide a stable funding platform from which to provide service. The new revenues would also support Health Canada in meeting internationally comparable service standards in these activities, thereby establishing predictability in the process for industry globally and timely access to these products by Canadians. Any increase in revenues would support the activities for which the fees were paid. Detailed descriptions of these fee activities are given in the “Activity Costs and Revenue Estimates” section, below.

After Parliamentary review of this Proposal, Health Canada will then need to secure authority from Treasury Board to retain these additional revenues and maintain the public funding currently dedicated to the programs. Expanding the total funding envelope is the only way to ensure that the Department can continue to meet its performance standards, particularly in light of the fact that Health Canada will then be subject to penalties for under performance, as required under the UFA.

*Auditor General’s Reports of 2004, 2006*

In March 2004, the annual report of the Auditor General, Chapter 2, highlighted concerns regarding the continued viability of the medical devices regulatory program. The report recommended that problems in the cost recovery program be resolved, whereby the actual costs of the program should be determined and fees be set based on those costs.

The November 2006 report of the Auditor General focused on the allocation of funds to regulatory programs. In this report, specific recommendations were made to review regulatory programs including the need to:

- Establish baseline information with regards to performance measurement;
- Set user fees that are based on clear and measurable service standards; and
- Review core funding to ensure that it is sufficient.
Specifically, on the issue of core funding, the Auditor General stated:

...programs that regulate these products need enough resources to ensure that Canadians are adequately protected from the risks to their safety and health.

This Proposal responds to the concerns of the Auditor General by updating the fees structure to assist in providing a sustainable base of funding for these activities.

4. Development of the Proposal

The Proposal aims to update the user fees regimes associated with the human drugs and medical devices programs. In support of this, it addresses fee structures, costing methodology, criteria for excluding or including activities for fees, impacts on business, fee mitigation measures, annual fee adjustments, and services standards. The Proposal has been developed by taking into consideration the results of the activity-based costing model, the analysis of cost drivers, international comparisons and consultation with stakeholders, including the reports of two independent advisory panels.

In the development of the Proposal, the UFA required the Department to:

- Determine that the activities were eligible for cost recovery;
- Explain how user fees were determined, including the cost-sharing rationale;
- Verify that fees and service standards were comparable to those in other relevant countries and provide, if required, the rationale for higher fees than internationally comparable regulator;
- Consult with clients and service users on regulatory services and associated user fees; and
- Establish, if requested, an independent advisory panel to address complaints pertaining to proposed user fees and service standards.

Activities eligible for cost recovery

The HPFB reviewed all its services and activities to determine which were appropriate for cost recovery. In order to be eligible, services and activities had to be legitimate and necessary functions of the Government of Canada, consistent with government commitments and result in a direct benefit to an external party. Consideration was also given as to whether or not the fee would result in a reasonable benefit to the Department that would outweigh the cost of administering it.

Activities or services were excluded from the framework if the implementation of fees was thought to unduly or unreasonably:

- Affect safety, access or innovation;
- Burden industry or other stakeholders;
- Target specific and exceptional groups;
- Jeopardize funding initiatives undertaken by other government organizations;
- Introduce legal complexities or impediments; or
- Require service standards that cannot be identified or achieved.

Examples of activities ineligible for cost recovery include:
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for Human Drugs and Medical Devices Programs

- Clinical trial applications and investigational testing applications and related adverse reaction reporting activities;
- Special access programs;
- Blood establishment licensing submissions and amendments;
- Emergency response; and
- Patent and litigation activities.

All other activities were considered appropriate for cost recovery and were considered in the development of the fees.

Cost-sharing ratio
To achieve an appropriate balance between funding sources (user fees revenues and public funding), a cost-sharing ratio was developed based on the relative benefit received by industry in relation to the public benefit derived from the activity. Each fee category was assessed according to factors such as safety or access to products for the public, financial or competitive advantage for the fee-paying industry, business or innovation development to address unmet health needs and ensuring compliance. Fees were defined accordingly, with the understanding that what is not covered by revenues from fees must be funded through the Department’s appropriations.

International Comparisons
The UFA requires a regulating authority to establish user fees that are comparable to those established by other countries with which a comparison is relevant and, against which the performance of the regulating authority can be measured. As a result, the HPFB undertook a review of four comparable regulatory regimes, all of which charge user fees for their activities. These regulators include: the United States (US), Australia, the European Union (EU) and the United Kingdom (UK), as a specific example of the application of EU legislation in a member country.

To support a meaningful comparison, an objective methodology was utilized and based on regulatory context, regulatory service or product, performance standards, type of clients/stakeholders and user fees. The review of Canadian regulatory frameworks and requirements concluded that the proposed service standards are internationally comparable with the four comparison jurisdictions, bearing in mind the fact that cost recovery approaches, regulatory organizational structures and legislated mandates vary across international jurisdictions.

While being generally comparable, there are a few areas where the proposed fees are higher than those in other countries, and the UFA requires that reasons be provided for these differences. Differences are generally as a result of different regulatory frameworks, fee structures or cost allocations. Canada regulates certain products differently than other jurisdictions, resulting in different regulatory commitments and levels of oversight.

For example, Canada is proposing fees for products that are not currently charged fees in the United States, including non-prescription and generic drugs; the US only charges fees for prescription drugs, and they are significantly higher than any proposed in Canada. However, there is currently a proposal being put forth in the US to begin charging fees for generic drug

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submissions in future. For device evaluation fees, the US charges less for pre-market notification submissions; however these submissions must meet fewer regulatory requirements than any comparable in Canada, thus making a direct fee comparison less appropriate.

Additionally, the variances between fee structures in some jurisdictions make direct comparisons challenging, especially for establishment licensing fees. In Australia, inspection and auditing activities for medical devices are structured differently than in Canada and fees are assigned for the establishment licence application, then additional fees are charged for the annual licence based on the type of product, as well as an hourly audit rate. Canada proposes a flat fee for each medical device company, regardless of how many inspection resources are used, number of sites or products are involved, and a component fee approach for drug establishments based on the activity performed at a specific building, regardless of how many inspection resources are used.

The proposed Canadian fees are based on the unit costs determined through comprehensive activity-based costing of resources required to provide the related regulatory activities and services. In the US, fees are not directly related to costs for associated activities, but for general program delivery and based on distributing revenues across fee categories, resulting, for example, in lower medical device establishment licences than those proposed in Canada.

The UK and Australia charge many additional fees for specific activities that Canada has included in more general fee categories. For annual drug product fees, one Australian fee is lower than that proposed in Canada. However, Australia does charge separate fees for certain activities such as review of advertising materials/issues, which were included in the costing and fee setting of the Canadian annual product licensing fee. For drug submission evaluation, some UK and Australian fees are lower than those proposed in Canada. The UK charges separately for scientific advice meetings, reclassifications and label assessments, and in Australia some components of policy and regulatory development work are not cost recovered. All these activities have been included in the costing and setting of the Canadian fees for specific submission categories rather than as separate activity fees, resulting in higher fees than those deemed directly comparable in the UK and Australia.

Amongst its international peers, in 2005-2006, Canada had a low regulatory cost-sharing level at approximately 28% for its human drug and medical device programs. This is in stark contrast to the cost-sharing levels of the United Kingdom (100%), Australia (100%), the European Union (70%) and the US (50%). Canada is also the only international jurisdiction that has not increased user fees since their implementation. As a result of this Proposal to Parliament, Health Canada intends to recover approximately 50% of the costs of its human drug and medical devices programs.

A detailed international analysis of cost recovery and service standards has been prepared. The documents International Comparison of Fees and Service Standards for Human Drugs (August 2007) and International Comparison of Fees and Service Standards for Medical Devices, (August 2007) are provided in the Background Binder (Tabs D and E). A brief review has been conducted and as of fiscal year 2009-2010, all four comparable regulators have raised their fees since the first international analysis was performed.

Consultation with Stakeholders
The HPFB actively engaged stakeholders in the development of the updated user fees through direct meetings as well as through publicly available documents and requests for input. An initial framework was developed in 2006-2007 and presented for consultation in April 2007. Consultations continued in 2007-2008 with the publication of the “Cost Recovery Framework: Official Notice of Fee Proposal for Human Drugs and Medical Devices”.

During the consultation process, several parties requested additional information on the approach used to establish costs. To ensure that all parties had access to more detailed information on the cost recovery methodology, a separate document entitled Cost Recovery Framework: Cost Development In Support of HPFB User Fees was prepared. It includes the information provided at the consultation sessions and a detailed description on how full costs were developed and how cost-sharing ratios were used to establish the proposed fee levels. This costing methodology document is provided in the Background Binder (Tab F).

Participants in the consultations included health product companies, industry associations, consumer and public interest groups, patient groups, academia and health professional associations. Comments received during these consultations have been considered in the development of this Proposal. Particularly, the Branch determined based on feedback from the April 2007 consultation that the Proposal would not include fees for natural health products. Further, after the publication of the Official Notice and the receipt of its subsequent feedback, fees for Good Clinical Practices applications were removed from the Proposal.

While the consultations were being conducted, a Business Impact Test (BIT) was conducted to identify any unintended and unexpected regulatory impacts on businesses. It was reported by a majority of those who responded that there would be some negative impact on their business, particularly with regard to the introduction of new product lines. However, many respondents agreed that cost recovery was a reasonable notion, if the subsequent revenues directly funded Health Canada activities in support of the health and safety of the Canadian public and the maintenance of or reduction in product approval times. The Executive Summary of the BIT is provided in Background Binder Tab G.

Establishment of Independent Advisory Panels (IAPs):
The UFA requires a department to establish, if requested, independent advisory panels to address complaints pertaining to proposed fees or service standards. The Department received such requests in response to the Official Notice. In follow up, two independent panels were established, one for human drugs and one for medical devices. The full reports of the IAPs can be found in Appendices C (Human Drugs) and D (Medical Devices).

Both panels supported the activity-based costing model and the majority of the cost-sharing rationales for fee categories. However, both panels also stated that their support of the updated fee regime was predicated on the Department keeping current appropriations if revenues were increased. All recommendations made by the IAPs were taken into consideration by the Department and several of them led to changes in the Proposal. Additionally, the panels made certain recommendations with which the Department did not agree. These instances are described in detail in the relevant sections of the Proposal. For a full account of Health Canada’s responses to the recommendations of the IAPs, please refer to Appendices E (Human Drugs) and F (Medical Devices).
5. Costing and Fee Structure

Costing
The proposed user fees were developed using an Activity-Based Costing (ABC) methodology which enabled the determination of accurate costing for regulatory activities. The ABC methodology is a cost accounting approach that assigns costs to activities based on their use of resources (e.g. labour resources, overhead, corporate costs). The approach is widely used in both public and private sector organizations.

The costing methodology followed by Health Canada is also in accordance with recommendations contained in the 2004 Report of the Auditor General which stated that costs of activities related to user fees must accurately reflect the full cost of those activities. The IAP for Human Drugs also supported the costing methodology and stated that the model provided a good baseline from which the Department can move forward to improve performance and efficiency. A document outlining the costing methodology is provided in the Background Binder (Tab F).

Fee Structure
The current fee structure for drug and medical device submission evaluations is linked to the submission type and is component-based, where individual fees are identified based on the type of information provided to support the submission, and added up to determine the total fee payable for any given submission.

The proposed revised fee structure establishes a flat fee for different categories. This reflects the average activity cost and level of effort associated with those groups of submissions; the type of submission is no longer relevant in fee calculations. The proposed flat fee structure applied to drugs and medical devices will simplify the determination of the fee to be charged, more effectively align that fee to respective costs and provide an increased level of cost certainty for fee payers.

The one area in which fees will not directly reflect the cost of service provision is in the submission evaluation fees for biologics. The cost of this service provision is higher than for pharmaceutical submission evaluations but the Department has decided to charge a single, consistent fee for both pharmaceuticals and biologics.

For annual drug product licensing, the current fee structure identifies different fees based on the type of product i.e. prescription, controlled substance, disinfectant, etc. The proposed revised fee structure establishes a flat fee for all products. The fee structure for medical device annual product licensing would remain unchanged. The establishment licensing fee structure for both drugs and medical devices would remain unchanged, as would the structures for file management.

6. Activity Costs and Revenue Estimates
The following sections outline the full costs of the fee activities as indicated in 2007 Official Notice, the associated proposed cost share for each and the estimated revenues to be collected, based on projections of 2010 workload.

Fee Mitigation
While fees are charged for regulatory services, Health Canada recognizes that in certain situations, fees might result in an undue burden on certain groups or individual fee payers. The approach of Health Canada to fee mitigation has always focussed on facilitating the availability of products to help Canadians maintain and improve their health, and to encourage innovation and access to new products. Therefore, a strong policy rationale exists to mitigate the undesirable impact of fees, particularly on smaller businesses. However, it is understood that fee mitigation impacts revenue expectations for the Department. Additionally, the Department has taken the position that foregone revenues through mitigation will not be cross-subsidized by other fee payers; the Department will fund the portion of these activities through appropriations. The projected revenues given below are those expected after the application of mitigation measures.

Appendices A (Human Drugs) and B (Medical Devices) to this document are provided that outline all fees, their associated service standards and proposed fee mitigation measures pertaining to regulatory activities for the programs.

Drug Evaluation (DEVAL): These activities relate to the evaluation of pharmaceutical and biologic drug submissions. 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 prior to its marketing in Canada. Examples of related activities include pre-submission meetings, screening, drug identification number work and product monograph review. It also permits the selective pre-market onsite evaluation and lot testing of products when warranted. The Official Notice identified the costs of these services to be $66.2 million.

The Department determined that while the fee payer does receive a substantial competitive advantage from evaluation, there is also a public benefit that is derived from these activities and therefore, that DEVAL user fees would recover 75% of the costs associated with the activities.

Although the cost of performing a submission evaluation for biologic drugs is higher than for pharmaceuticals, the Department acknowledges the concern regarding the fee differential. Health Canada will waive the differential and charge the same fee for both pharmaceuticals and biologic drugs, recognizing the potential disproportionate impact on the numerous small businesses in the biotech sector.

Additionally, at this time fees for Notifiable Change (Drug Submission Evaluation) submissions will not be introduced due to the current program performance, which is such that the charging of fees for service would be inappropriate. Therefore, based on 2010 workload projections, revenues from updated DEVAL fees are projected to be in the range of $49.1 million, after mitigation, in the first full year of implementation.

Drug Establishment Licensing (DEL): The DEL is a key compliance tool used to assess whether the regulated party has met the regulatory requirements. An annual licensing fee is charged to
cover compliance activities such as site and facility inspections to evaluate the suitability of establishments to engage in production, distribution or testing of drugs.

Drug establishments are inspected to assess whether licensable activities are being conducted in accordance with Good Manufacturing Practices requirements. Some drug establishments will also be inspected to determine if requirements for security measures and record keeping are being followed with respect to narcotics and controlled drugs. Additionally, the inspection may require that samples are collected and analyzed in a lab. All Canadian drug establishments must hold a DEL to fabricate, package, label, distribute, import, wholesale, or test a drug. Fees are charged for the initial license, subsequent annual licenses and the reinstatement of a license. The Official Notice identified the costs of these services to be $13.9 million.

In 2002, a change was made to the Food and Drug Regulations requiring that each building be issued a DEL. Previously, a DEL would be issued to a site, which included all buildings within a 1km radius, and the amount invoiced for the site was based on the highest cost activity. Under this Proposal, the revised fees will be charged for each building, consistent with the current requirements outlined in the Food and Drug Regulations.

When the benefit criteria were applied to the DEL activities, it was determined that this licence provides industry with significant benefits such as the ability to undertake business in Canada, and to gain competitive advantage in Canada and abroad. While the public derives some benefit from these activities, it is very small in comparison to the financial benefit gained by industry. Therefore, it was determined that the DEL fees would recover 100% of the costs to provide the service.

The IAP on Human Drugs accepted this percentage but did recommend that the burden of DEL fees should be reduced for the medical gas industry. To address the uniqueness of this industry, the Department has consulted with that sector on options. Based on the feedback, the Department will pursue amendments to the fee regulations to reduce the impact of the proposed fees for most medical gas companies.

Overall, based on 2010 workload projections, revenues from updated DEL fees are expected to be in the range of $21.9 million, after mitigation, in the first full year of implementation.

Drug Authority to Sell (DATS): Through this regulatory activity, Health Canada monitors the large number of products for sale on the market through post-market surveillance, as well as compliance and enforcement. The annual fee allows a manufacturer to continue to sell an approved or licensed product in Canada. The Official Notice identified the costs of this service to be $36.9 million.

When the benefit criteria were applied to DATS, it was determined that both fee payers and the general public benefit from the provision of DATS services. The general public benefits in that these fees support the monitoring of a large number of products for sale on the market through post-market surveillance, as well as compliance and enforcement. However, these activities also benefit industry as the DATS provides authority to industry to sell a product in Canada which results in profits and competitive advantage. Because the provision of the DATS benefits both
the general public and the fee payer, it was determined that the costs of providing the service would be shared equally.

However, the Independent Advisory Panel for Human Drugs expressed concern over the allocation of 43% of costs to be recovered under this fee to post-market surveillance and adverse drug reaction monitoring. It also expressed concerns that these activities do not provide a private benefit to the fee payer, as required by the UFA, and do not have adequate performance standards.

In response, the Department maintains that a service standard has been implemented for the issuance of a DATS licence and is proposed to be maintained (e.g. 120 days to process annual notification). Additionally, Health Canada is also in the process of developing additional performance standards for post-market surveillance and will consult with industry and other key stakeholders prior to implementation (anticipated 2011-12). Health Canada will subsequently examine the option of incorporating them in the next review of user fees.

Additionally, the Panel felt that certain groups of drugs (i.e. disinfectants, non-prescription drugs) would be charged a disproportionate amount in relation to the costs associated with those specific groups. Health Canada is of the view that the likelihood or nature of post-market surveillance activities is not necessarily linked to the type of product. Health Canada is also of the view that the benefits received by the industry from activities relating to these fees are significant. Annual product licensing provides companies with the ability to collect revenues in Canada. Funding from these fees supports activities that support the regulation of a 'level playing field', thereby providing competitive advantage.

Recognizing the private benefit of these activities, Health Canada believes 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 and that greater efficiency is developed and applied to the manner in which the regulatory function is carried out. Because of the above reasons, Health Canada proposes to maintain the fees and structure, with a 50% cost sharing ratio for the annual DATS fees as presented in the Official Notice of Fee Proposal, July 2007. Therefore, based on 2010 workload projections, revenues from updated DATS fees are expected to be in the range of $12.9 million, after mitigation, in the first full year of implementation.

**Drug Master Files (DMF):** The activity involved in the development of DMF includes processing, reviewing and administration of the file. DMF contain information that is referenced in the evaluation of a product regarding the manufacturing of ingredients that are used in a product. DMF are developed at the request of a company, in order to increase the number of producers to which it can sell its products. The administration of these activities is conducted mainly to facilitate trade among the industry. The Official Notice identified the cost of this service to be $0.3 million.

The services described above are non-regulatory voluntary services that provide fee payers with national and international marketing advantage. As there is no advantage to the general Canadian public, it was determined that industry would carry 100% of the costs.
based on 2010 workload projections, revenues from updated DMF fees are expected to be in the range of $0.60 million, after mitigation, in the first full year of implementation.

Certificates of Pharmaceutical Product (CPPs) have been removed from this Proposal subsequent to the publication of the Official Notice in 2007. Like DMF, fees for CPP are non-regulatory and paid for a voluntary service. This certificate indicates the compliance status of a drug against Good Manufacturing Practice requirements and facilitates Canadian interests abroad by supporting export activities. Given that these certificates have no function in the review, licensing, compliance monitoring or surveillance of products or establishments in Canada, CPPs have been removed from this Proposal and will be reviewed separately.

**Medical Device Evaluation (MDEVAL):** This activity includes the medical/scientific evaluation of medical device licenses and amendment applications for assessment of the safety and effectiveness of the devices before marketing in Canada. The Official Notice identified the costs of these services to be $9.6 million.

The fee payers receive significant competitive and financial advantage in obtaining a licence to distribute a product in Canada. Canadians also share in the benefit of this service as they enjoy confidence that they have access to safe, effective and high quality medical devices. It was determined that 75% of the cost of providing the MDEVAL service would be paid by industry.

The IAP on Medical Devices recommended that fee mitigation measures for MDEVALs be amended to include a 2.5% cap of the first two years on the market for devices with less than $100K in sales and a 1% cap for sales under $50K. The Department supports this recommendation in principle, recognizes the need for appropriate mitigation and acknowledges stakeholders concerns that the proposed measures are not sufficient. Current mitigation measures include a 5% cap, as did the Official Notice. Implementation of the Panel’s recommendation would result in fewer companies qualifying for mitigation, but increase the amount of mitigation for those who do qualify.

This recommendation of the IAP would also result in more Class II devices not qualifying for mitigation. To address the principle of the Panel’s recommendation to provide greater mitigation to smaller companies, the mitigation measures in this Proposal have been amended for application review to include a fee cap of 2.5% of the first two years on the market for devices with less than $100K in sales. Therefore, based on 2010 workload projections, revenues from updated MDEVAL fees are expected to be in the range of $7.7 million, after mitigation, in the first full year of implementation.

**Medical Device Establishment Licensing (MDEL):** The MDEL is a key compliance tool used to assess whether the regulated party has met the regulatory requirements. Fees are charged to cover compliance activities such as site and facility inspections and to determine if documented procedures are in place, where applicable, related to distribution records, complaint handling, recalls, mandatory problem reporting and for handling, storage, delivery, installation, and servicing with respect to the medical devices intended for sale. The Official Notice identified the costs of these services to be $13.9 million.
Establishment licensing for medical devices provides a world recognizable standard of excellence that allows industries to gain competitive advantage in producing or distributing their products not only in Canada but around the world. While the public obtains some benefit from this, it is relatively small in comparison to the benefit received by industry.

MDEL fees were originally set at 100% of full costs. However, a majority recommendation of the Independent Advisory Panel on Medical Devices suggested a 75% cost share. The Department has proposed that the cost share be established at 85% in recognition that the profile of the medical device sector includes a significant number of stakeholders that may require additional support. Based on 2010 workload projections, revenues from updated MDEL fees are expected to be in the range of $12.0 million, after mitigation, in the first full year of implementation.

Medical Device Authority to Sell (MDATS): Through this regulatory activity, Health Canada monitors the large number of medical devices on the Canadian market through post-market surveillance, stakeholder communication, policy and technology development, quality management oversight, product-testing and laboratory analysis. The annual fee is paid for the right to maintain and sell medical devices in Canada, excluding those classed as the lowest risk. The Official Notice identified the cost of these services were to be $12.7 million.

Fee payers and the public benefit from the provision of MDATS services. The public benefits in that these fees support the monitoring of a large number of products for sale on the market through post-market surveillance, as well as compliance and enforcement. However, these activities also benefit industry as the MDATS provides authority to industry to sell a product in Canada which results in profits and competitive advantage. Because the provision of the MDATS benefits both the general public and the fee payer, it was determined that the costs of providing the service would be shared equally (50% cost recovered). Therefore, based on 2010 workload projections, revenues from updated MDATS fees are expected to be in the range of $8.2 million, after mitigation, in the first full year of implementation.

Annual Fee Adjustments
The July 2007 Official Notice of Fee Proposal presented a blended index that would be calculated and applied annually to all fee categories. The Independent Advisory Panel for Human Drugs recognized the conflicting positions of Health Canada (inflationary costs impacting resources) and industry (automatic and unjustified increases without process efficiencies). However, the Panel recommended that instead of annual inflationary adjustments a collaborative approach between the Branch and industry should be considered with a view to achieving efficiencies. The Panel also suggested that an evaluation of the program be performed within a three to five-year period and adjustments be made at that time.

The Department maintains that an annual adjustment factor is necessary to ensure that service standards continue to be met. Such an adjustment is consistent with other international jurisdictions, such as the United States, Australia and the United Kingdom which all make annual adjustments to their fees to reflect changing costs and workload.

The Department will, however, employ techniques and approaches to improve program efficiencies. The imposition of penalties for missed service standards will be a significant
incentive to ensure resources are effectively managed. Additionally, Health Canada will review the costs associated with the fees every three years and will propose new or amended fees to reflect the results of these reviews.

A flat percentage increase of 2% is now being proposed, based on the average calculation for the past five years using the method described in the July 2007 Official Notice of Fee Proposal (i.e. blended index); this differs from the original proposal in which the blended index would be calculated and applied annually. Every year, a notification will be provided in the Canada Gazette II with the revised fee schedules, reflecting the adjusted fees.

**Total Projected Revenues**

If user fees are modernized as described in this Proposal, and applied against 2010 workload projections, the expected new revenues will represent an increase of approximately $65.4 million from the current receipts in Year 1. The total expected revenues by the Department in the first full year of implementation, post-mitigation, will be $112.4 million. As costs are projected to be $227.8 million for 2010-2011, this ratio restores the original cost share of 50%. Overall, total revenues to be generated by this Proposal are expected to be in the order of $112.4 million, $114.6 million and $116.9 million over the first three full years of implementation.

| Projected Costs* and Revenues** based on 2010 Workload (Millions) |
|-----------------|-----------------|-----------------|
|                 | Year 1          | Year 2          | Year 3          |
| Costs           | $227.8          | $244.9          | $262.1          |
| Revenue         | $112.4          | $114.6          | $116.9          |

*based on trending of published costs in the Departmental Performance Report
**based on 2% annual increase with no adjustment for workload

7. **Conclusion**

This Proposal has been developed for the purpose of updating user fees for the human drugs and medical devices programs in order to reflect current costs, to provide stable and sustainable resourcing of these regulatory programs and to respond to the Auditor General’s reports of 2004 and 2006 regarding program sustainability. These efforts will support an appropriate balance of public-private cost sharing and will relieve the general Canadian taxpayer of the burden of subsidizing activities for which industry receives direct benefits. This approach has taken into consideration the views of stakeholders throughout the process and will keep Canada in line with international counterparts.