Final Report

Audit of Cost Recovery of Health Products

June 2015

Table of Contents

Executive summary

Health Canada (the Department) is the federal regulator responsible for assessing the safety, quality and efficacy of drugs, medical devices and other therapeutic products, as mandated by the *Department of Health Act,* the *Food and Drugs Act* and the *Food and Drug Regulations*. Funding for regulated cost-recoverable activities related to human drugs and medical devices comes from a combination of public funds (appropriations) and revenues collected from the private sector for user-fee services. The implementation of the regulatory framework for health products falls under Health Canada's Health Products Program, and the Health Products and Food Branch is responsible for this file.

The objective of this audit was to assess the effectiveness of the management control framework in place to support the cost-recovery activities for health products and to ensure compliance with the relevant acts and regulations. The scope of the audit included cost-recovery activities related to the *Fees in Respect of Drugs and Medical Devices Regulations*. The audit was conducted in accordance with the Internal Auditing Standards for the Government of Canada and the International Standards for the Professional Practice of Internal Auditing.

The audit concluded that the management control framework in place to support cost-recovery activities for health products and to ensure compliance with the relevant acts and regulations needs minor improvement.

The branch has a governance structure in place that ensures adequate oversight of the cost recovery of human health products. Roles and responsibilities are defined and communicated and senior management receives complete and timely information to support day-to-day decision-making. However, the Department would benefit from receiving year-over-year detailed costing information that would enable management to determine the timing of user-fee renewals. In March 2015, the branch implemented a new governance structure with a view to streamlining and improving decision-making by the Branch Executive Committee (BEC).

With respect to risk management, day-to-day operational and financial risks on cost-recovery activities are communicated through dashboards and management variance reporting. The management of operational, regulatory and policy issues that require longer-term solutions could be strengthened through the regular review and update of a permanent risk register.

Overall, the tracking and reporting systems provide complete, accurate and timely information on user-fee revenues and the cost of user-fee activities. The internal controls could be strengthened further by implementing a process for fee remission eligibility, by modifying the Establishment Licences (EL) renewal date in the regulations to align with the business cycle and by reviewing the Drug Establishment Licences (DEL) user-fee structure to improve its alignment with the associated costing model, so that DEL user fees can be clearly identified and explained in future user-fee renewal initiatives.

Overall, performance information is monitored and reported against user-fee service standards. Responsibilities for the screening and first review of Class III and IV medical device applications should be delegated to independent parties. With respect to the management of financial resources, the revenues collected were allocated against corresponding user-fee activities within the Drugs and Medical Devices Sub-programs.

Management agrees with the six recommendations and has provided an action plan that will strengthen the management control framework supporting the cost-recovery activities for health products.

A - Introduction

1. Background

Health Canada (the Department) is the federal regulator responsible for assessing the safety, quality and efficacy of drugs, medical devices and other therapeutic products, as mandated under the *Department of Health Act*.

As per the Department's 2013-14 Report on Plans and Priorities, the development, maintenance, and implementation of a regulatory framework for health products falls under Health Canada's Health Products Program, under strategic outcome No. 2: "Health risks and benefits associated with food, products, substances, and environmental factors are appropriately managed and communicated to Canadians."

The mandate of the Health Products and Food Branch (HPFB) is to take an integrated approach to managing the health-related risks and benefits of health products and food. HPFB's Health Products Program is supported by four sub-program activities:

- Pharmaceutical Drugs: This program sub-activity regulates pharmaceutical drugs for human and animal use, including prescription and non-prescription drugs, disinfectants and sanitizers with disinfectant claims.
- Biologics and Radiopharmaceuticals: This program sub-activity regulates biological products (products derived from living sources) for human use. Some of the products regulated include blood and blood products, viral and bacterial vaccines, gene therapy products, tissues, organs and xenografts, which are manufactured in Canada or elsewhere.
- Medical Devices: This program sub-activity regulates medical devices for human use. Medical devices cover a wide range of health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical conditions in humans.
- Natural Health Products: This program sub-activity provides the regulatory framework to develop, maintain and implement the Natural Health Products Program, which includes herbal remedies, homeopathic medicines, vitamins, minerals, traditional medicines, probiotics, amino acids and essential fatty acids.

The main legislation and policies related to the cost recovery of health products include the *Financial Administration Act,* the *Department of Health Act*, the *User Fees Act,* the Treasury Board *Policy on Special Revenue Spending Authorities*, the *Fees in Respect of Drugs and Medical Devices Regulation* and the *Food and Drug Regulations*.

The regulated activities for human drugs and medical devices for which fees are collected are grouped into six distinct fee lines, as follows:

- Drug evaluation;
- Drug establishment licences;
- Drug right to sell;

- Medical device evaluation;
- Medical device establishment licences;
- Medical device right to sell.

Descriptions of these activities are provided in Appendix C.

HPFB is supported by other branches in the delivery of user-fee activities. The Regions and Programs Bureau (RAPB) conducts compliance and enforcement activities for health product fabrication, packaging and labelling, distribution, importation, testing and wholesale facilities, mainly through inspection services required for the delivery and renewal of Drug Establishment Licences (DEL) and Medical Device Establishment Licences (MDEL). It also provides compliance verification services. The Chief Financial Officer Branch (CFOB) and the Corporate Services Branch (CSB) provide functional support (finance, IT and HR).

User-fee activities are funded through a combination of public funds (appropriations) and user-fee revenues paid by applicants (vote netting authority). User fees were introduced for human health products in the mid-1990s. By 2010, the proportion of public funding for human health products regulatory activities had grown from 50% to over 75%.

In 2006-07, HPFB undertook to renew the user fees for human drugs and medical devices, and developed an activity-based costing model to determine the full unit cost of regulatory services. A cost-recovery framework was developed and industry consultations were conducted in accordance with the requirements of the *User Fees Act* (UFA). This led to a Proposal to Parliament in 2010 for User Fees and Service Standards for Human Drugs and Medical Devices Program. As per the proposal, user fees were established in order to achieve an appropriate balance between public and private funding sources for each fee line. Cost-sharing ratios were developed based on the relative benefit received by industry in relation to the public benefit derived from the regulated activities.

Revised *Fees in Respect of Drugs and Medical Devices Regulations* were implemented in 2011-12. See Appendix D and Appendix E for a schedule of the service standards and fees, along with performance results since the implementation of the new regulations. The Department's net voting authority to collect and re-spend user-fee revenues was increased in 2011.

The 2010 Proposal to Parliament included projected revenues and the full cost of regulated activities for human drugs and medical devices. Table 1 compares revenues and costs initially forecast, as well as forecasts and actual costs from 2010-11 to 2013-14.

Table 1: Costs and revenues (unaudited)

		Total Costs ('000,000)	Total Revenue ('000,000)	Cost recovery ratio
2010-11 (old user fees)	**Actual**	$172.0	$48.9	**28%**
2011-12	**Initial forecast**	$227.8	$112.4	**49%**
	Actual	$203.5	$73.8	**36%**
2012-13	**Initial forecast**	$244.9	$114.6	**47%**
	Revised forecast	$207.6	$83.3	**40%**
	Actual	$202.1	$81.8	**41%**
2013-14	**Initial forecast**	$262.1	$116.9	**45%**
	Revised forecast	$206,1	$88,3	**43%**
	Actual	$211.5	$84.2	**41%**

Sources of information:
Initial forecast: Health Canada's Proposal to Parliament for User Fees and Service Standards for Human Drugs and Medical Devices Programs (Tabled in 2010); Revised forecast and Actual: Departmental Performance Report and financial reports provided by Branch Senior Financial Officer.

2. Audit objective

The objective of the audit was to assess the effectiveness of the management control framework in place to support the cost-recovery activities for health products and to ensure compliance with the relevant acts and regulations.

3. Audit scope

The scope of the audit focused on cost-recovery activities undertaken during fiscal year 2013-2014. It included cost-recovery activities related to cost-recovery fees for human drugs and medical devices. The audit examined governance, risk management and controls in place to monitor annual costs, fee revenue, performance against service standards and the impact of user fees on budget management.

The scope did not include natural health products, since there are no cost-recovery fees associated with these products. As well, veterinary drugs were not included because these drugs do not fall under the *Fees in Respect of Drugs and Medical Devices Regulations*.

4. Audit approach

The audit approach included a review of the legislative framework (acts, regulations and policies), as well as departmental documentation such as terms of reference, records of decisions, procedures documents, the costing methodology, internal and external financial and performance reporting documents, interviews, observations and inquiry. The approach also included testing and analysis of transactions within the six major fee categories, as outlined in Appendix C, to assess the accuracy of the financial and performance information provided to management.

The audit criteria, outlined in Appendix A, were derived from relevant acts, regulations, TB policies and the Office of the Comptroller General – Internal Audit Sector's Audit Criteria

Related to the Management Accountability Framework: A Tool for Internal Auditors (March 2011).

The audit was conducted in accordance with the Government of Canada's *Policy on Internal Audit*. It examined sufficient, relevant, reliable and useful evidence, thus obtaining sufficient information and explanations to provide a reasonable level of assurance in support of the audit conclusion. The fieldwork was performed at Health Canada's headquarters.

5. Statement of conformance

In the professional judgment of the Chief Audit Executive, sufficient and appropriate procedures were performed and evidence gathered to support the accuracy of the audit conclusion. The audit findings and conclusion are based on a comparison of the conditions that existed as of the date of the audit, against established criteria that were agreed upon with management. Further, the evidence was gathered in accordance with the Internal Auditing Standards for the Government of Canada and the International Standards for the Professional Practice of Internal Auditing. The audit conforms to the Internal Auditing Standards for the Government of Canada, as supported by the results of the quality assurance and improvement program.

B - Findings, recommendations and management responses

1. Governance

1.1 Governance structure and oversight

Audit criterion: *There is a governance structure in place that ensures oversight of the cost recovery of health product-related activities and supports the delivery of results.*

An effective governance structure is essential to ensure that regulated cost-recoverable activities are managed and monitored in a way that supports the delivery of the Health Products and Food Branch's (HPFB) regulatory services for human drugs and medical devices in accordance with applicable acts, policies and regulations. The delivery of specific user-fee services includes multiple steps and requires input from multiple business units within Health Canada (the Department) (see Appendix F). Processes vary in complexity, contingent upon the level of dependency among stakeholders, the innovative nature, quality and quantity of data provided with applications and the timing and complexity of billing and revenue collection.

At the inter-branch level, the **Assistant Deputy Minister Revenue Management Committee** (ADM-RM) is the highest-level decision-making forum for the management of user-fee revenues. The chair is the ADM of HPFB and membership includes the ADM of the Corporate Services Branch (CSB), the Chief Financial Officer (CFO), the Senior Director General of the Regions and Programs Bureau (RAPB) and the Director General of the Resource Management and Operations Directorate (RMOD). Meetings are held quarterly or at the instigation of HPFB's ADM, and attendance can vary as required. The ADM-RM makes inter-branch revenue allocation decisions annually and revenue collections and variances from forecasts are monitored during the fiscal year. Although there are no terms of reference for this committee, ADM-RM meeting agendas, discussions and decisions are documented.

Within HPFB, the **Branch Executive Committee** (BEC) is the highest-level decision-making body. It is responsible for the coherent and strategic overall management of the branch's resources and policies, as well as its corporate responsibility for achieving objectives. Members meet on a monthly basis and its mandate is to provide leadership and to set direction on and monitor strategy, policy and risks, to ensure results. Its secretariat function is provided by the RMOD. Membership includes the ADM of HPFB (Chair) and all directors general (DG) within HPFB. BEC receives dashboards on a regular basis, which provide financial, operational and performance information on human drugs and medical devices for cost-recovery activities. HPFB financial performance information is communicated to BEC through the management variance reporting (MVR) process. BEC meeting agendas, discussions and decisions are formally documented.

The **Branch Operations Committee** (BOC) brings strategic orientation and an integrated approach to the branch management and operations, with a broad mandate to focus on internal management and operational policies, processes and initiatives, as well as corporate

management matters. It is chaired by the DG of the RMOD. The other members are the directors from each directorate within the branch, a representative from the Human Resources Directorate and the Branch Senior Financial Officer. The audit reviewed the terms of reference and a sample of agendas and records of decisions and found that the operations related to the programs are routinely discussed.

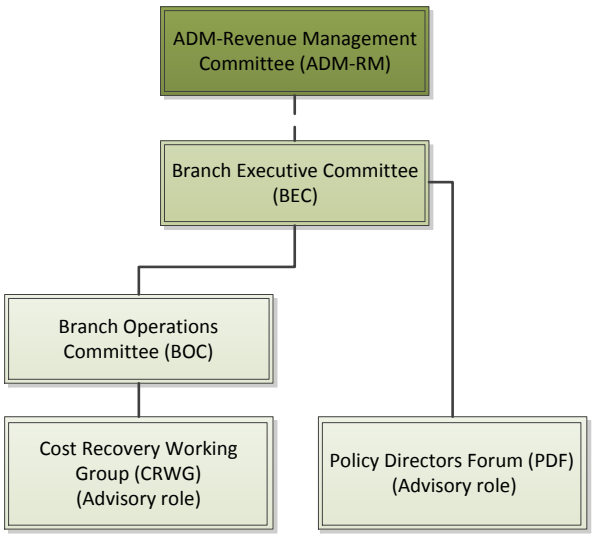
The **Policy Directors Forum** (PDF) plays an advisory role to BEC. It is chaired by the Director of the Policy, Planning and International Affairs Directorate. Membership consists of a director from each directorate with a mandate focused on program policy issues, including those related to cost recovery. Meetings take place on an ad hoc basis; cost-recovery policy issues are discussed and recommendations are made to BEC.

At the operational level, the **Cost Recovery Working Group** (CRWG) discusses issues related to user-fee activities at the directorate level and makes recommendations to BOC and BEC. Although CRWG is not a decision-making body, it plays a key role in providing expert advice to management on cost-recovery issues. The terms of reference (ToR) include developing baseline costing data for all branch activities, in support of multiple branch purposes such as reviewing existing fees and proposing updates and improving efficiencies in user-fee administration. Specifically, the working group develops baseline costing data at the directorate level aimed particularly at cost-recovery activities. The working group is chaired by a representative of the RMOD, with membership from all HPFB directorates. The Health Products and Food Branch Inspectorate (the Inspectorate) is the program lead that represents the RAPB's interests with respect to activity costing.

Since the implementation of the 2011 user-fee regulations, the role of CRWG has evolved and is more focused on providing support to directorates on emerging regulatory matters, facilitating the development of analytical tools related to baseline costing data and providing recommendations to senior management on policy issues. The ToR for CRWG have not been updated since May 2012, and numerous items are no longer being pursued (for example, the Branch Cost-recovery Project Plan; zero-based budgets). As well, the frequency of meetings has changed from bi-weekly to monthly. The branch would benefit from updating the ToR for CRWG, to ensure that its mandate, deliverables and reporting structure are aligned with current branch priorities.

Figure 1 presents the governance structure prior to March 2015.

Figure 1: Governance structure prior to March 2015



On March 18, 2015, the branch unveiled a new governance model with a view to streamlining and improving decision-making, better aligning with the Department's governance structure and increasing BEC's focus on strategic decision-making (see Appendix G). It will be supported by three subcommittees.

- The Sub-committee on Integrating Policy, Programs and Science (BEC-IPPS) will be responsible for providing support to various branch initiatives throughout their development and aligning them with other branch priorities. These initiatives include the development of policies, legislations, regulations, programs and international and scientific projects.

- The Sub-committee on Transformation, Transparency, Investments and Finance (BEC-TTIF) will work towards improving branch efficiency and effectiveness by addressing financial questions, including the planning and creation of investment plans.

- The Sub-committee on Talent and People Management (BEC-TPM) provides solutions for matters affecting HPFB's staff.

The audit found that the governance structure in place ensures adequate oversight of the activities pertaining to the cost recovery of health products and supports the delivery of results. HPFB would benefit from updating the terms of reference of CRWG. However, given that a new governance structure has recently been put in place, no recommendations will be made at this time.

1.2 Roles and responsibilities

Audit criterion: *Roles and responsibilities are defined and communicated.*

In reviewing roles and responsibilities, the audit expected that accountabilities would be clearly established, communicated and understood, and that processes related to the inputs required from the various branches, directorates and divisions for the coordination of work, data collection, analysis and reporting existed and were effective.

The **Health Products and Food Branch** (HPFB) has primary responsibility for managing the health-related risks and benefits of health products, including the development of a management framework for the recovery of the costs of regulated activities for human drugs and medical devices.

HPFB regulation activities pertaining to human drugs and medical devices include the pre-market evaluation and post-market monitoring of the safety, quality and efficacy of drugs, vaccines, medical devices and other therapeutic products. Pre-market activities include the issuance of Medical Device Licences, Drug Identification Numbers (DIN) and Establishment Licences. Post-market activities include the surveillance and monitoring of licenced drugs and medical devices, as well as compliance and enforcement activities, to ensure that regulated parties meet regulatory requirements before Establishment Licences can be renewed.

Regulated activities for human drugs (pharmaceutical drugs, biologics and radiopharmaceuticals) and medical devices for which fees are collected are grouped into six distinct fee lines, as follows:

- Drug Evaluation (DEVAL, Pharma and Biologic);
- Drug Establishment Licences (DEL);
- Drug Right to Sell (DRTS);
- Medical Device Evaluation (MDEVAL);
- Medical Device Establishment Licences (MDEL);
- Medical Device Right to Sell (MDRTS).

A description of these activities is provided in Appendix C.

Directorates within the branch are responsible for delivering on the activities for a specific fee line, as illustrated in Appendix F.

The **Therapeutic Products Directorate** (TPD) regulates pharmaceutical drugs (DEVAL - Pharma) for human use and medical devices (MDEVAL). Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality, as required by the *Food and Drugs Act* and the *Food and Drug Regulations*.

The **Biologics and Genetic Therapeutics Directorate** (BGTD) regulates biological drugs (DEVAL - Bio) and radiopharmaceuticals for human use in Canada, whether manufactured in

Canada or elsewhere. Prior to being given market authorization, a manufacturer must present substantive scientific evidence of a product's safety, efficacy and quality, as required by the *Food and Drugs Act* and the *Food and Drug Regulations*.

The **Marketed Health Product Directorate** (MHPD**)** is responsible for coordinating and implementing a consistent approach to the conduct of post-market surveillance monitoring, assessing and intervening on all regulated marketed drugs and medical devices. Some of the cost of these activities is funded through user fees for the annual renewal of product licences (DRTS and MDRTS).

The **Health Products and Food Branch Inspectorate** (the Inspectorate) manages and delivers a national compliance and enforcement program for blood and donor semen; cells, tissues and organs; drugs (human and veterinary); medical devices; and natural health products. It is also responsible for managing the compliance and enforcement program at the national level for all products under the mandate of HPFB, with the exception of food products. The Inspectorate works in collaboration with the Regions and Programs Bureau (RAPB), which conducts the site inspections required for renewing Drug and Medical Device Establishment Licences, as well as compliance verification activities. The Inspectorate also works in collaboration with the National Laboratory Program, which provides scientific expertise and analytical results to support border integrity activities, inspections, compliance verifications and investigations for drugs, natural health products and some medical devices.

The **Policy, Planning and International Affairs Directorate's** (PPIAD**)** mandate is to provide leadership in developing and advancing the branch's policy and international agenda. This includes policy development on horizontal issues; legislative and regulatory modernization; activities to increase Canada's influence as a global regulator; and science policy integration.

The mandate of the **Resource Management and Operations Directorate** (RMOD) is to enhance the branch management framework, to ensure the fulfillment of HPFB's management and stewardship obligations with respect to branch resources and to ensure that all branch managers have the tools they need to effectively manage programs. Specifically, the RMOD provides horizontal branch-wide coordination and guidance on the consistent, efficient and effective management of operations and resources for the human drugs and medical devices programs.

The RMOD has played a key role in supporting directorates during the implementation phase of the new fee regulations, the modernization of the activity structure used in the current costing model and the implementation SAP-PS, a time-tracking system that allows employees to record their time against pre-determined activities. The RMOD continues to support directorates and the branch in the management of emerging user-fee issues. The RMOD also collects and reviews performance and operational information from the directorates, which is consolidated into dashboards and presented to senior management at BOC and BEC meetings.

HPFB is supported by other branches in the delivery of user-fee activities. The Chief Financial Officer Branch (CFOB) and the Corporate Services Branch provide functional support (finance, IT and HR).

The audit reviewed documentation such as organization charts, terms of reference for committees, divisional operations plans and operational guidance documents related to various user-fee activities. Interviews with staff confirmed that the roles and responsibilities for activities such as departmental performance reporting management variance reporting, and dashboards were defined and communicated with respect to ownership, preparation, presentation, review and approval.

The audit found that roles and responsibilities were defined and communicated among the different business units, working groups and committees, and procedures and guidelines to facilitate the management of user-fee activities and decision-making were in place.

1.3 Information for decision-making

Audit criterion: *Senior management receives complete, timely and accurate information to support decision-making.*

It is essential that governance bodies receive accurate and timely information to support planning, monitoring, risk management and decision-making. Complete, timely and accurate information is necessary to facilitate decision-making for day-to-day operations, as well as for long-term planning such as the renewal of user fees.

Operational information related to workloads and backlogs, performance against service standards and the financial situation are gathered and approved at the directorate level. This information is then consolidated by the RMOD into dashboards for the review and approval of the ADM on a monthly basis and the Deputy Minister on a quarterly basis. Financial position and forecast information is reviewed and approved at the cost-centre level up to the branch level during the management variance reporting (MVR) process. The Branch Senior Financial Officer (BSFO) presents the branch's financial situation to the ADM for his approval. It is then provided to the BEC members for information. The audit found that operational information contained in the dashboards and financial reports was timely, complete and supported decision-making.

Current user fees are based on specific private/public cost-sharing ratios for each distinct fee line, which were determined on the principle of achieving a reasonable balance between private and public funding. These ratios were agreed upon by the industry, the Department and the Treasury Board of Canada Secretariat (TBS) through discussion and negotiation.

User-fee revenues and the full cost by fee line are published annually in the Departmental Performance Report (DPR) tables, as required by the *User Fees Act* (UFA). A review of DPR tables showed that since the implementation of the new regulations, which included a 2% annual increase of user fees, revenues collected since 2011 have not been as high as expected and the initial cost-recovery ratios have not been met (see Table 2 for details).

Table 2 – Analysis of cost-recovery ratios

Fee lines	Before Proposal	After Proposal				Private/ Public Benefit Ratio, as per Proposal*
	Actuals 2010-12	Actuals 2011-12	Actuals 2012-13	Actuals 2013-14	3-year Average, by User Fee	
Drug Evaluation (DEVAL)	29%	37%	45%	46%	43%	75%
Medical Devices Evaluation (MDEVAL)	34%	34%	39%	32%	35%	75%
Drug Establishment Licences (DEL)	39%	50%	47%	47%	48%	100%
Medical Devices Establishment Licences (MDEL)	36%	81%	56%	69%	69%	85%
Drug Authority To Sell (DATS)	16%	16%	20%	20%	19%	50%
Medical Devices Authority To Sell (MDATS)	36%	61%	75%	57%	64%	50%

* Current user fees are based on specific private/public cost-sharing ratios for each distinct fee line, which were determined on the principle of achieving a reasonable balance between private and public funding. These ratios were agreed upon by the industry, the Department and TBS through discussion and negotiation.

HPFB has developed a formal process for forecasting and analyzing revenues at the fee category level (see Section 3.1). Tracking of the time spent on cost-recovery activities is captured in the time-tracking system, in some cases all the way down to the submission level; efforts are underway to develop unit costing tools (see Section 3.2).

As part of 2010 Proposal to Parliament, Health Canada committed to reviewing its fees and costs for services after three years. In keeping with this commitment, HPFB released the 2014 Review of the *Fees in Respect of Drugs and Medical Devices Regulations*. This report provides an overview of activities over the last three years and makes reference to increasing instances where submissions are becoming more complex, contain more clinical trial data and require a greater level of effort to review. However, no costing information is provided to indicate the impact of these cost drivers. Although there are efforts underway to develop cost analytical tools, there is no formal process to analyze and benchmark year-over-year costs at the fee category level. Such information is key to enabling management to develop a forward-looking strategy and determine if and when the renewal of current fees is warranted.

Senior management receives complete and timely information to support day-to-day decision-making. Analysis and benchmarking of year-over-year cost at the fee category level would enable management to determine the timing of user-fee renewal.

Recommendation 1

It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, develop a formal process to analyze and benchmark year-over-year costs at the fee category level, to support management in determining the timing of user-fee renewal.

Management response

Management agrees with the recommendation and will formalize its analysis process to further inform the timing of user-fee renewal.

Annual costs and revenues are reported annually in the Departmental Performance Report. Analyses of variances are also conducted annually. Health Canada committed in the Regulatory Impact Analysis Statement of the fee regulations that a review of the fees and costs would occur every three years and may propose new or amended fees to reflect the results of these reviews. The first Cost Recovery Review was published in October 2014, with the next review expected to be completed and published in 2017-18, including unit costs at the fee category level. Revising fees requires extensive consultation and tabling in Parliament, and generally takes two to four years to implement.

2. Risk management

2.1 Risk management

Audit criterion: *Risks that impact the cost recovery of health products are identified, assessed, documented and managed on an ongoing basis.*

In reviewing risk management practices, it was expected that processes would be in place to identify, assess, communicate, mitigate and monitor risks related to cost-recovery activities.

Annually, risk issues are captured through the Report on Plans and Priorities, Business Continuity Plans and branch operational plans. The branch reports that risks are discussed in various committees. However, new risks have emerged since the implementation of the 2011 Regulations. In many cases, the level of effort required to process submissions is increasing due to the growing complexity of the science behind new drugs and medical devices. In addition, anticipated private/public benefit ratios for user-fee revenues have yet to be realized, and the impact on revenues of fee mitigation measures continues to be material. These risks create financial and operational pressures for which the Department must take measures, to ensure that its regulatory commitments can be met on an ongoing basis.

The audit found that financial management risks are documented, communicated and approved by managers and directors, DGs and the ADM at the branch level through management variance reporting (MVR). Risks related to revenue collection are also discussed at ADM-RM meetings. Risks associated with operations and performance against service

standards are documented and communicated through the use of consolidated dashboards that are approved by the DGs and are presented to the ADM monthly and the Deputy Minister quarterly, for their review and approval.

Risks associated with operational, regulatory and policy issues are identified through an informal process within each directorate. These items are then referred to the appropriate DG on a case-by-case basis, as needed, depending on the significance of the issue. Issues that are not resolved at the DG level are referred to the RMOD, which records the issue on a permanent list referred to as the Parking Lot, for future consideration. A review of documents provided by the RMOD demonstrated that most of the issues identified during the audit were recorded. However, some documents were not dated, issues were neither prioritized by risk level nor assigned to a division or person, and potential actions, required approvals and timelines were not identified. This type of list is an important risk management tool that helps to prioritize the actions required for the future renewal of user fees.

The audit observed that day-to-day operational and financial risks on cost-recovery activities are well managed through the dashboards and management variance reporting. However, HPFB should strengthen the management of issues that require longer-term solutions by developing and maintaining a permanent risk register that is reviewed and updated on a regular basis.

Recommendation 2

It is recommended that Assistant Deputy Minister, Health Products and Food Branch, develop a permanent risk register to strengthen the management of issues that require longer-term solutions.

Management response

Management agrees with the recommendation and will build a risk register for cost-recovery issues.

HPFB will develop a risk register, which will inform longer-term planning.

3. Internal controls

3.1 User-fee revenue

Audit criterion: *Tracking and reporting systems provide complete, accurate and timely information on user-fee revenues.*

It is important that processes and systems be put in place to support the accurate and timely recording, tracking, collection and reporting of user-fee revenues, thus enabling proper oversight of revenue management.

User-fee revenues are generated from the processing of applications and submissions received from industry throughout the year. The *Food and Drug Regulations* contain provisions that stipulate the fee amount to be invoiced and the timing of the payment for each fee line (see Appendix D and Appendix E). User fees consist mostly of a uniform rate for submissions and applications within a fee category, with the exception of DEL fees, which are based on the number of "components" included on a licence application. HPFB develops annual revenue forecasts for each fee category, based on historical activity volumes and on forward-looking information received from industry. Once revenue forecasts have been approved, they are allocated to HPFB, RAPB, CFOB and CSB through SAP as annual budgeted amounts. Once revenue amounts have been budgeted, only cash from the collected revenues can be re-spent, and there is always a risk of shortfall between actual collections and forecast revenues. The timing of payments is not uniform across all fee lines and some fees are collected in a different fiscal year than the year in which the work was completed. In the case of drug submissions, when fees exceed $10,000, 75% of revenues are collected before an application or submission has been fully processed. As such, the processing of some submissions can be carried out over more than one fiscal year. In order to ensure proper matching of revenues and expenditures, HPFB defers to the following year the portion of revenue that has not been earned during the current fiscal year.

Directorates delivering user-fee services are responsible for the accuracy of the invoices issued. Although applicants submit payment for user fees with their application, the final amount to be invoiced is determined and entered into SAP by the division staff involved in the screening of drug and medical device submissions or the processing of annual renewal applications for product and establishment licences. Invoices are produced through SAP. Each type of user fee for each fee line is assigned a material code that is mapped to a pre-determined general ledger (GL) account in SAP. SAP reports provide revenue information by fee line or material code. Payments received by the directorates are sent to CFOB for immediate deposit.

Collected revenues are allocated among HPFB, RAPB, CFOB and CSB, based on pre-established proportions approved by the ADM-RM. HPFB then reallocates revenues to the various directorates and divisions that conduct user-fee activities. Appendix H details the allocation of revenues by fee line and by branch for 2013-14. Section 3.4 of this report provides further explanations on the management of financial resources.

The audit included a review of applicable regulations, invoicing processes and controls, and tested revenue transactions from all fee lines. The audit found that, overall, the tracking and reporting systems provide complete, accurate and timely information on user-fee revenues. However, the audit observed the following:

- The Establishment Licence (EL) renewal date creates cash management challenges associated with revenues arriving at the end of the fiscal year.
- The complexity of the Drug Establishment License (DEL) fee structure creates the potential risk of invoicing errors.
- There is no established process for fee remission eligibility (that is, a reduction of fees).

Establishment Licence renewal date

Current regulations require that applications and the payment of user fees for the annual renewal of ELs be submitted by licence holders before April 1 of each year, causing significant revenues to be received at the end of the fiscal year. As such, the processing of the EL renewal applications received at the end of the fiscal year is likely to be performed in the following fiscal year. As revenues cannot be carried from one fiscal year to the next, there are cash management challenges associated with revenues arriving at the end of the fiscal year. It is difficult to predict an amount for the user fees to be collected from renewals before the end of a given fiscal year and at the beginning of the new fiscal year (April 1), thus reducing the stability and predictability of EL revenues to fund EL activities. In the case of ELs, in 2012, this resulted in approximately $5 million in revenue being received after March 31, 2012, but linked to licences from the previous fiscal year (that is, 2011-12). This situation repeated itself with a greater impact in 2012-13, with $9 million collected in the subsequent fiscal year, namely 2013-14.

Since 2013-14, in an effort to review applications and collect the associated revenues within the same fiscal year, HPFP has been encouraging clients to submit their EL annual review applications prior to mid-February, to facilitate timely application processing and the issuance of an invoice. This allows the Inspectorate to renew a large percentage of licences and collect revenues before fiscal year-end. Management has indicated that efforts are underway to address the issue by requesting that the renewal date in the *Food and Drug Regulations* be modified.

Complexity of Drug Establishment License fee structure

The audit observed that component-based invoicing of DELs is a complex and tedious manual process. It requires a good understanding of the user-fee structure in order to determine the total fees for each application, creating the potential for human error. The Inspectorate acknowledged that the fee structure is complex and that simplifying it would reduce the potential risks of invoicing errors. In Section 3.2 of this report, Recommendation 5 addresses the fact that the DEL user-fee structure and the costing model's activity structure need to be better aligned to support the determination of future fees. This initiative would provide an opportunity for HPFB to simplify the DEL fee structure and reduce the potential risks of invoicing errors.

Remission of user fees

New fee mitigation measures were introduced in the revised fee regulations to address situations where fees might result in an undue burden on certain groups or individual fee payers. The Department's approach to fee mitigation focuses on facilitating the availability of products, to help Canadians maintain and improve their health, and to support access to new products. For example, fee remissions are available to businesses with a small revenue stream. New businesses may seek a deferral of fee payment, and special dispensation is given for drugs and medical devices intended to be sold for international humanitarian purposes. However, it is understood that fee mitigation impacts revenue expectations. As shown in

Table 3, the impact of fee mitigation has increased from 14% of full user fees in 2011-12 to 20% in 2013-14.

Table 3 – Analysis of fee remissions

Remission	2011-12		2012-13		2013-14	
	$ remitted	% of revenue	$ remitted	% of revenue	$ remitted	% of revenue
DEVAL	$110,809	<1%	$411,407	1%	$99,445	<1%
MDEVAL	$136,853	2%	$270,128	4%	$210,600	3%
DRTS	$3,437,969	27%	$4,000,554	25%	$4,246,334	25%
MDRTS	$2,343,880	26%	$2,941,174	25%	$3,335,602	27%
DEL	$1,420,750	9%	$1,615,180	10%	$2,173,412	15%
MDEL	$4,562,381	36%	$4,408,768	36%	$12,004,643	53%
Total	$12,012,641	14%	$13,647,211	12%	$22,070,036	20%

Source: 2014 Review of the *Fees in Respect of Drugs and Medical Devices Regulations* (Unaudited)

Current regulations allow applicants to request a fee remission (that is, a reduction in fees) based on a percentage of gross revenue or product sales. Such a request requires applicants to submit financial information supporting the fee remission request, as well as an attestation as to the veracity of the information provided. The Department can also request that audited financial information be provided by an applicant. During a review of the invoicing process, the audit noted that there is no tool to guide staff in determining if audited financial information should be requested. Given that fee remissions have a significant impact on revenues, HPFB would benefit from implementing a risk assessment process to determine when audited financial information will be requested from applicants.

In conclusion, overall, the systems in place provide complete, accurate and timely information for tracking and reporting on user-fee revenues. However, the audit observed that because of the renewal date of Establishment Licences, HPFB is experiencing cash management challenges associated with revenues arriving at the end of the fiscal year. Furthermore, the audit observed the absence of a process for fee remission eligibility. Lastly, the audit noted an opportunity to simplify the DEL fee structure in order to reduce the potential risks of invoicing errors (see Recommendation 5).

Recommendation 3

It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, modify the Establishment Licence renewal date in the Food and Drug Regulations *so that the services can be provided in the year during which the revenues are collected.*

Management response

Management agrees with the recommendation and expects that moving the date will improve the predictability and availability of revenues to fund establishment licensing activities in the year when revenues are collected.

The current April 1st date in the *Food and Drug Regulation*s for Establishment Licence renewals results in cash management challenges, as significant revenue arrives at the end of the fiscal year. HPFB will propose a date and initiate informal discussions with stakeholders. The process to revise regulations is complex and is dependent on departmental priorities.

Recommendation 4

It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, develop and implement a risk assessment process to determine when audited financial information should be requested from applicants requesting a fee remission.

Management response

Management agrees with the recommendation and that a risk assessment process would be appropriate to determine when to request audited sales records.

A significant number of companies and products apply and qualify for fee remissions based on small revenue streams, resulting in a significant impact on revenues available to Health Canada. The Minister has the authority to request audited sales records to substantiate a fee remission request. A strategy will be developed and a pilot project will be conducted, involving a small sample. Assessment of the findings and the pilot will inform the final strategy and process.

3.2 Activity costing

Audit criterion: *Tracking and reporting systems provide complete, accurate and timely information on the full cost of user-fee activities in support of decision-making.*

Costing systems provide management with the raw data required to track and report on the cost of activities in support of operational and long-term decision-making. It was expected that systems would be in place to record and report on operating costs for in-year financial management purposes, as well as for planning future activities. It was also anticipated that the activity costing process would provide sufficient detail to accurately identify and analyze costs associated with the structure of the user fees, as required under the UFA, in order to provide management with information that would inform strategic decision-making regarding future user-fee improvements.

Section 4.(1) paragraph (d) of the UFA also requires that before a regulating authority fixes, increases or expands the application of or increases the duration of a user fee, it must clearly explain to clients how the user fee is determined and identify the cost and the structure of the user fee.

Costing information is produced through two major systems. First, operating expenditures and revenues are recorded and reported through various SAP modules. This system is used by the Department to generate monthly trial balances and financial management reports. HPFB's financial information reporting is entered by branch, directorate, division and bureau, and includes user-fee revenues and expenditures from cost-recoverable and non-cost-recoverable activities. Due to coding limitations, SAP is unable to distinguish and report specifically on cost-recoverable activities versus non-recoverable activities, and therefore cannot be used alone to determine user-fee activity costs required to determine user fees.

Second, HPFB employees, as well as the RAPB employees working on Inspectorate program activities, record time worked in the SAP - Project Systems, Cross-Application Time Sheets (SAP-PS/CATS). This system was implemented in 2011 to capture accurate information regarding the time and effort expended on all branch activities, in order to understand the effort and resources required to perform activities. Specifically, SAP-PS/CATS focused on providing reliable data to determine complete activity costs, so that detailed unit costing could be developed to support future user-fee modernization initiatives and for DPR user-fee reporting purposes.

The RMOD, in cooperation with staff in the directorates and the divisions, has developed an activity structure and related coding that defines categories of cost-recoverable and non-cost-recoverable activities. The activity structure has been incorporated into SAP-PS/CATS and activity coding is mapped to relevant elements in SAP. For some activities, SAP-PS/CATS can record salary costs down to the submission level. Salary costs represent approximately 85% of HPFB's total expenditures.

Costing of compliance and enforcement activities

Drug and Medical Device Establishment Licences (DEL and MDEL) fees are determined based on the cost of compliance and enforcement activities. Section 4(1) paragraph (d) of the UFA requires that departments clearly explain to clients how a user fee is determined and identify the cost and revenue elements of that user fee. While the costing model clearly aligns activities and the user-fee structure for the other fee lines, the audit found that the activity structure for compliance and enforcement activities does not clearly align with the user-fee structure of Drug Establishment Licence (DEL) user fees. It should be noted that the same observation was made regarding the 2007 costing model used to develop DEL fees for the 2010 Proposal.

Improvements are required to the DEL user-fee structure and the costing model's activity structure, to ensure that they are aligned and that the costs used to determine DEL user fees can be clearly explained in future user-fee renewal initiatives. This initiative could also serve

as an opportunity to simplify the DEL user-fee structure and reduce the potential for invoicing errors, as mentioned in Section 3.1 of this report.

SAP-PS data analysis and unit costing

Since the implementation of SAP-PS in 2011, HPFB has made significant progress on improving time recording compliance by encouraging directorate staff to record their time promptly in the SAP-PS system.

Since 2013-14, as part of phase 3 of HPFB's cost-recovery roadmap, more emphasis has been placed at the directorate operational level on the analysis of SAP-PS data, to develop unit costing methods that allow for an analysis of labour cost fluctuations and other operational metrics. This initiative, coordinated through CRWG, is still at an early stage. As mentioned previously, the 2014 Review of the *Fees in Respect of Drugs and Medical Devices Regulations* states that there are an increasing number of instances where submissions are more complex, contain more clinical trial data and require a greater level of effort to review; however, the report does not substantiate this statement with actual numbers. The development of unit costing tools is essential in order to understand the impact on business and have the information necessary to support future user-fee renewal initiatives. The audit found that efforts and progress in developing unit costing tools vary in scope and depth among directorates. HPFB would benefit from ensuring that efforts toward the implementation of unit costing tools are consistent across all directorates.

Prior to 2013-14, DPR user-fee revenues and costs were determined by using information from SAP. Starting in 2013-14, salary costs were determined using SAP-PS data, while revenues and non-salary operating costs were obtained from SAP and allocated as in previous years. The audit found that the process used to determine 2013-14 DPR revenues and costs provided accurate and timely information.

Overall, the tracking and reporting systems provide complete, accurate and timely information on the complete cost of user-fee activities in support of decision-making. However, improvements could be made to the activity structure for the compliance and enforcement activities that drive DEL fees, in compliance with Section 4(1), paragraph (d) of the UFA.

Recommendation 5

It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, review the Drug Establishment Licence (DEL) user-fee structure, to improve its alignment with the associated costing model, so that DEL user fees can be clearly identified and explained.

Management response

Management agrees with the recommendation and will review and address the complexity of the DEL fee structure, which has multiple components dependent on, for example, activity, drug category and dosage form.

The revenue from the DEL fees supports the delivery of the national compliance and enforcement program, including good manufacturing practices inspections; it is not a fee-for-service. The fee will be restructured to more accurately reflect the level of effort for the different licensable activities. Revising fees requires extensive consultation and tabling in Parliament, and generally takes two to four years to implement.

3.3 Performance against services standards

Audit criterion: *Performance results are monitored and reported against user-fee service standards.*

Meeting performance requirements is crucial to satisfying industry expectations and to maintain a stable source of funding through the collection of user fees. During the audit, it was expected that processes and controls would be in place to measure, evaluate and report on performance against service standards in a timely and accurate manner, and to inform management on results and risk factors in support of planning and decision-making.

As per the UFA, financial penalties can be incurred in the form of reduced fees if the Department fails to meet its service standards in respect of a user fee, within certain parameters. Therefore, the Department's ability to manage operations and meet the service standards outlined in Appendix D and Appendix E is essential.

The UFA requires that before a regulating authority fixes, increases or expands the application of or increases the duration of a user fee, it must establish standards against which the performance of the regulating authority can be measured. As well, the UFA stipulates that fees will be reduced when the performance achieved in a fiscal year fails to meet the service standard by an amount in excess of 10% above the standard. Another requirement of the UFA is that the Minister will report annually on the actual performance levels that have been reached against established service standards.

Performance information is tracked by fee line through multiple systems. The information is recorded in the appropriate system by divisional staff responsible for specific processes. Performance tracking and monitoring of individual submissions and applications is reviewed by management at all levels within the branch. This process ensures that work loads are managed, performance standards are met or appropriate action can be taken to address slippage.

The audit included a review of selected files from the various fee lines and tested performance data recorded in the relevant tracking system. The audit found that overall, the performance results were monitored and reported against user-fee service standards.

However, improvements are required to strengthen the performance tracking for medical device applications. As well, the audit noted that the branch would benefit from improving DPR supporting documentation for DELs and MDELs.

The Therapeutic Products Directorate's (TPD) Medical Devices Bureau is responsible for processing medical device submissions. As indicated in the guidance document entitled Management of Applications for Medical Device Licences and Investigational Testing Authorizations, all medical device submissions are tracked from the time they are received to the final decision. Therefore, when a medical device application is received, it first goes through a screening process to determine if it is administratively and technically acceptable to proceed to the review phase. A screening acceptance letter (Class III and IV applications) is issued at the end of the screening process, which marks the beginning of the review phase.

Performance related to medical device submissions reported in the DPR is based on the number of calendar days required for a first review. The first review decision can result in a licence being issued, the issue of a letter requesting additional information or a refusal. First review time is tracked from the moment a screening acceptance letter is issued, but does not include screening time. Performance related to the screening process is tracked and reported internally only.

During a review of performance tracking for Class III and IV submission files, the audit found that screening targets were often exceeded for the files tested, and the performance targets for the first review phase were largely met. The audit noted that responsibility for the technical screening and review of Class III and IV applications falls to the same evaluation division, which differs from practices in TPD pharmaceutical review division. To ensure an effective approach regarding review practices within TPD and to strengthen performance tracking and reporting, a process should be established whereby the activities of screening and first review of Class III and Class IV medical device applications are clearly separated.

In conclusion, overall, performance information is monitored and reported against user-fee service standards. However, improvements are required to strengthen the performance tracking and reporting for medical device applications.

Recommendation 6

It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, establish a process whereby the activities of screening and first review of Class III and IV medical device applications are clearly separated.

Management response

Management agrees with the recommendation. To reduce any misperceptions, HPFB agrees that a clear separation of responsibilities for screening and review may strengthen the integrity of the process.

The screening of an application is intended to identify if the application is administratively and technically acceptable. A screening pilot is currently underway to determine the viability of completing initial screening completely within the Device Licencing Services Division, rather than having some of the technical screening completed within the review areas.

3.4 Management of financial resources

Audit criterion: *Financial resources are allocated and re-allocated against corresponding user-fee activities.*

Funding from cost-recoverable activities comes from a combination of appropriations and revenues collected from the private sector for user-fee services. Once user-fee revenues have been invoiced and collected, the BSFO first redistributes the user-fee revenues proportionally among the stakeholder branches (HPFB, RAPB, CFOB and CSB), based on each branch's share of the full cost of activities. This allocation is approved annually (or as required) by the ADM-RM. Revenues are then allocated by each branch to its operating units, to cover corresponding activity costs. See Appendix F and Appendix H for details on the organizational structure and the allocation of user-fee revenues.

The *User Fees Act* (UFA) requires that a report be presented to Parliament that sets out the total amount of user fees collected by fee line, the costs that the user fee covered, the established performance standards and the actual performance levels reached. The audit found that the Department has met this obligation by publishing the required information in the supplementary tables of the annual DPR.

The TB *Policy on Special Revenue Spending Authorities* states that departments must ensure that expenses incurred to produce services are directly related to the revenue produced through the sale of these services. Revenues must be spent on the intended uses, and there can be no cross-subsidization. The Department has the authority to re-spend revenues collected, pursuant to the user-fee regulations for the Human Drugs and Medical Devices Programs. In 2015, the Department issued a Financial Information Bulletin which provides guidance on the management of revenues generated by the Drugs and Medical Devices programs.

The bulletin indicates that revenues generated from Drugs and Medical Devices are to be maintained within the Program Alignment Architecture (PAA) Sub-programs: Drugs (PAA 2.1.1 and 2.1.2) and Medical Devices (PAA 2.1.3), in alignment with how the fees are defined and charged. Revenue will not be reallocated to programs outside of those being cost-recovered.

The audit reviewed relevant documentation supporting the revenue allocations and found that the revenues collected were allocated against corresponding user-fee activities within the Drugs and Medical Devices Sub-programs.

C - Conclusion

The audit concluded that the management control framework in place to support cost-recovery activities for health products and to ensure compliance with the relevant acts and regulations needs minor improvement.

The audit also found that the branch has a governance structure in place that ensures adequate oversight of the cost recovery of human health products. Roles and responsibilities are defined and communicated and senior management receives complete and timely information to support day-to-day decision-making. However, the Department would benefit from receiving year-over-year detailed costing information that would enable management to determine the timing of user-fee renewals. In March 2015, the branch implemented a new governance structure with a view to streamlining and improving decision-making by the Branch Executive Committee (BEC).

With respect to risk management, day-to-day operational and financial risks on cost-recovery activities are communicated through dashboards and management variance reporting. The management of operational, regulatory and policy issues that require longer-term solutions could be strengthened through the regular review and update of a permanent risk register.

Overall, the tracking and reporting systems provide complete, accurate and timely information on user-fee revenues and the cost of user-fee activities. However, the internal controls could be strengthened further by implementing a process for fee remission eligibility, by modifying the EL renewal date in the regulations to align with the business cycle and by reviewing the DEL user-fee structure to improve its alignment with the associated costing model, so that DEL user fees can be clearly identified and explained in future user-fee renewal initiatives.

Overall, performance information is monitored and reported against user-fee service standards. Responsibilities for the screening and first review of Class III and IV medical device applications should be delegated to independent parties. With respect to the management of financial resources, the revenues collected were allocated against corresponding user-fee activities within the Drugs and Medical Devices Sub-programs.

The areas for improvement that have been noted will collectively strengthen the management control framework, to better support the cost-recovery activities for health products at the Department.

Appendix A – Lines of enquiry and criteria

Audit of the Cost Recovery of Health Products		
Criteria Title		**Audit Criteria**
Line of Enquiry 1: Governance		
1.1	Governance structure and oversight[1]	There is a governance structure in place that ensures oversight of the cost recovery of health product-related activities and supports the delivery of results.
1.2	Roles and responsibilities[1]	Roles and responsibilities are defined and communicated.
1.3	Information for decision-making[1]	Senior management receives complete, timely and accurate information to support decision-making.
Line of Enquiry 2: Risk management		
2.1	Risk management[1]	Risks that impact the cost recovery of health products are identified, assessed, documented and managed on an ongoing basis.
Line of Enquiry 3: Internal controls		
3.1	User-fee revenue[2,3,4]	Tracking and reporting systems provide complete, accurate and timely information on user-fee revenues.
3.2	Activity costing [2, 3, 4]	Tracking and reporting systems provide complete, accurate and timely information on the full cost of user-fee activities in support of decision-making.
3.3	Performance against service standards[3,4]	Performance results are monitored and reported against user-fee service standards.
3.4	Management of financial resources [5]	Financial resources are allocated and re-allocated against corresponding user-fee activities.

[1] OCG Audit Criteria Related to the Management Accountability Framework: A Tool for Internal Auditors
[2] *User Fees Act*, Section 4.1d
[3] *User Fees Act*, Section 7
[4] *User Fees Act*, Section 5.1
[5] TB *Policy Suite on Financial Management*; TB Policy on Special Revenue Spending Authorities

Appendix B – Scorecard

Audit of the Cost Recovery of Health Products								
Criterion	**Rating**						**Conclusion**	**Rec #**
Governance								
1.1 Governance structure and oversight							There is a governance structure in place to provide oversight and to support the delivery of results. However, the branch would benefit from updating the terms of reference of the Cost Recovery Working Group.	-
1.2 Roles and responsibilities							Roles and responsibilities are defined and communicated.	-
1.3 Information for decision-making							Management receives complete and timely information to support day-to-day decision-making. However, the Department should also receive year-over-year revenue and cost information to determine the timing of user-fee renewals.	1
Risk management								
2.1 Risk management							Day-to-day operational and financial risks are well managed. However, a permanent risk register should be developed to strengthen the management of issues that require longer-term solutions.	2
Internal controls (rating by fee lines for criteria 3.1, 3.2 and 3.3)								
(see Appendix C for description of fee lines activities)	**DEVAL**	**DEL**	**DRTS**	**MDEVAL**	**MDEL**	**MDRTS**	**DEVAL**: Drug evaluation **DEL**: Drug establishment licences **DRTS:** Drug right to sell **MDEVAL:** Medical device evaluation **MDEL:** Medical device establishment licences **DRTS:** Medical device right to sell	
3.1 User-fee revenues							Overall, the tracking and reporting systems provide complete, accurate and timely information on user-fee revenues. However, the DEL and MDEL renewal date should be modified in the regulations to align with the business cycle. Moreover, a risk assessment process to determine fee remission eligibility for all fee-lines activities should be developed and implemented. There is an opportunity to simplify the DEL fee structure in order to reduce the potential risk of invoicing error.	3, 4 Refer to 5
3.2 Activity costing							Overall, the tracking and reporting systems provide complete, accurate and timely information on the full cost of user-fee activities. However, a review of the DEL user-fee structure should be conducted to improve its alignment with the associated costing model, so that DEL user fees can be clearly identified and explained in future user-fee renewal initiatives.	5

Audit of the Cost Recovery of Health Products								
Criterion	**Rating**						**Conclusion**	**Rec #**
(see Appendix C for description of fee lines activities)	**DEVAL**	**DEL**	**DRTS**	**MDEVAL**	**MDEL**	**MDRTS**	**DEVAL**: Drug evaluation **DEL**: Drug establishment licences **DRTS:** Drug right to sell **MDEVAL:** Medical device evaluation **MDEL:** Medical device establishment licences **DRTS:** Medical device right to sell	
3.3 Performance against service standards							Overall, performance information is monitored and reported against user-fee service standards. However, improvements are required to strengthen the performance tracking and reporting for medical device applications. The branch would benefit from improving DPR supporting documentation for DELs and MDELs.	6
3.4 Management of financial resources							The revenues collected were allocated against corresponding user-fee activities, within the Drugs and Medical Devices Sub-programs.	-

Satisfactory | Needs Minor Improvement | Needs Moderate Improvement | Needs Improvement | Unsatisfactory | Unknown; Cannot Be Measured

Appendix C – User fees and associated activities

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.

Drug Establishment Licences (DEL): These activities are directly related to one of Health Canada's key compliance and enforcement tools. Compliance with regulatory requirements is assessed through inspection, which is the basis for the issuance of the Establishment Licence. A DEL is required to authorize an establishment that is proposing to conduct or is conducting a regulated activity. Fees are charged for the initial licence, annual licence reviews, licence amendment and the reinstatement of a licence.

Drug Right to Sell (DRTS): This annual fee allows a manufacturer to continue to sell an approved or licenced product in Canada. Health Canada monitors the large number of drugs for sale on the Canadian market through post-market surveillance, stakeholder communication, policy and technology development, quality management oversight, product-testing and laboratory analysis as well as compliance and enforcement.

Medical Device Evaluation (MDEVAL): These activities relate to the medical/scientific evaluation of medical device licences and amendment applications. Fees are charged to review and evaluate scientific documentation in support of demonstrating the safety and effectiveness of the devices before marketing in Canada.

Medical Device Establishment Licences (MDEL): These user fees support facility based authorization for establishments proposing to engage in or are engaged in the importation or sale of medical devices and manufacturers of the lowest risk medical devices. A Medical Device Establishment Licence provides authorization for the regulated party to conduct a controlled activity in Canada at disclosed sites. Fees are charged for the initial licence, annual licence review and the reinstatement of a licence.

Medical Device Right to Sell (MDRTS): This is an annual fee for the authorization to maintain and sell medical devices in Canada, excluding those classed at the lowest risk. Activities supported by this fee include, but are not limited to: post-market surveillance, stakeholder communication, policy and technology development and quality management oversight.

(Source: 2010 Proposal to Parliament)

Appendix D – Service standards, fees and performance results for Drug Evaluation

Source of information: Services standards: Canada Gazette, Vol. 148, No. 11 – March 15, 2014; Services fees: Health Canada Departmental Performance Reports for the fiscal years from 2011-12 to 2013-14

Drug Evaluation:
The Drug Evaluation category represents Health Canada's authorization activities that permit a manufacturer to sell its product in Canada. There are numerous different types and categories of products and changes to products that require Health Canada authorization. For example: biological drugs or chemical (pharmaceutical) drugs; brand name drugs or generic pharmaceutical drugs; new drugs or old drugs; adding a new indications or changing a manufacturing site. The size and complexity of these different drug evaluations are very diverse and different performance standards are required to represent that diversity. The complex performance reporting below represents the diverse products and drug evaluation types that are submitted by various sub-sectors of the drug industry.

Performance:
Average time in calendar days to issue the first review decision (Review 1). Items that did not meet the performance standard are marked in *red*.

The *User Fees Act* requires a fee reduction equivalent to the unachieved performance where performance results are in excess of the service standard by more than 10% (to a maximum of 50% of the user fee). The reduced user fee applies from the day upon which the annual report for the fiscal year is tabled to the day upon which the next annual report is tabled.

User Fees (Fee Lines)	Fee Class and Type	Fee with Penalties as of November 6, 2013	Fee as of April 1, 2014	New User-Fee Service Standards, effective April 1, 2011 (days)	Performance Results (days)		
					2011-12	2012-13	2013-14
Drug Evaluation Fees (DEVAL)	**Pharmaceuticals**						
	New Active Substance		$322,056				
	New Active Substance : New Drug Submission (NAS: NDS)			300	220	256	268
	Clinical or Non-Clinical data and Chemistry & Manufacturing data		$163,120				
	CLIN C&M: NDS (New Drug Submission)			300	236	*302*	291
	CLIN C&M: SNDS (Supplement to a New Drug Submission)			300	235	271	293
	Clinical or Non-Clinical data only		$76,132				
	CLIN : NDS (New Drug Submission)			300	-	-	297
	CLIN: SNDS (Supplement to a New Drug Submission)			300	226	266	276
	CLIN: DIN A (Drug Identification Number)			210	188	160	205
	Comparative Studies Chemistry & Manufacturing data		$46,016				
	COMP C&M: NDS (New Drug Submission)			180	175	154	-
	COMP C&M: ANDS (Abbreviated New Drug Submission)	$23,910	$24,388	180	172	*264*	*196*

User Fees (Fee Lines)	Fee Class and Type	Fee with Penalties as of November 6, 2013	Fee as of April 1, 2014	New User-Fee Service Standards, effective April 1, 2011 (days)	Performance Results (days)		
					2011-12	2012-13	2013-14
Drug Evaluation Fees (DEVAL)	COMP C&M: SANDS (Supplement to an Abbreviated New Drug Submission)	$22,557	$23,008	180	177	*340*	*191*
	COMP C&M: SNDS (Supplement to a New Drug Submission)			180	159	175	174
	COMP C&M: DIN A (Drug Identification Number)			210	-	210	193
	Chemistry & Manufacturing data only		$21,756				
	C&M: NDS (New Drug Submission)			180	-	110	178
	C&M: ANDS (Abbreviated New Drug Submission)	$15,144	$15,447	180	121	*233*	*288*
	C&M: SANDS (Supplement to an Abbreviated New Drug Submission)			180	132	*198*	149
	C&M: SNDS (Supplement to a New Drug Submission)			180	115	150	157
	C&M: DIN A (Drug Identification Number)			210	201	117	177
	Published Data		$18,041				
	PUBLISHED DATA: SNDS (Supplement to a New Drug Submission)			300	243	213	262
	PUBLISHED DATA: DIN A (Drug Identification Number)			210	-	200	159
	Switch Status from Prescription Drug to Non-Prescription Drug		$43,808				
	Rx to OTC Switch: SNDS (Supplement to a New Drug Submission)			180	-	167	172
	Disinfectants		$4,055				
	DISINFECTANT: NDS-D (New Drug Submission-Disinfectants)			300	-	266	*327*
	DISINFECTANT: SNDS-D (Supplement New Drug Submission-Disinfectants)			300	-	-	290
	DISINFECTANT: DIN D 180 (Drug Identification Number)			180	7	-	-
	DISINFECTANT: DIN D 210 (Drug Identification Number)			210	181	194	210
	Labelling Only		$2,931				
	LABELLING ONLY : NDS (New Drug Submission)			60	47	56	50
	LABELLING ONLY : ANDS (Abbreviated New Drug Submission)			60	-	58	48
	LABELLING ONLY : SANDS (Supplement to an Abbreviated New Drug Submission)			60	27	32	29
	LABELLING ONLY : SNDS (Supplement to a New Drug Submission)			60	46	54	52
	LABELLING ONLY : DIN A			180	103	127	127
	Drug Identification Number Application - Labelling Standard		$1,625				
	LABEL STANDARD: DIN A (Drug Identification Number)			45	32	32	37
	LABEL STANDARD: DIN D (Drug Identification Number)			45	22	35	42
	LABEL STANDARD: DIN F (Drug Identification Number)			45	32	34	34
	Administrative Submission		$303				
	ADMINISTRATIVE: NDS (New Drug Submission)			45	31	22	29
	ADMINISTRATIVE: ANDS (Abbreviated New Drug Submission)			45	30	21	28
	ADMINISTRATIVE: SANDS (Supplement to an Abbreviated New Drug Submission)			45	30	24	30

User Fees (Fee Lines)	Fee Class and Type	Fee with Penalties as of November 6, 2013	Fee as of April 1, 2014	New User-Fee Service Standards, effective April 1, 2011 (days)	Performance Results (days)		
					2011-12	2012-13	2013-14
Drug Evaluation Fees (DEVAL)	ADMINISTRATIVE: SNDS (Supplement to a New Drug Submission)			45	33	35	31
	ADMINISTRATIVE: DIN A (Drug Identification Number)			45	16	21	20
	ADMINISTRATIVE: DIN D (Drug Identification Number)			45	17	32	32
	Biologics						
	New Active Substance		$322,056				
	NAS NDS (New Drug Submission)			300	238	230	239
	Clinical or Non-Clinical data and Chemistry & Manufacturing data		$163,120				
	CLIN C&M: NDS (New Drug Submission)			300	244	275	280
	CLIN C&M: SNDS (Supplement to a New Drug Submission)			300	291	296	264
	CLIN C&M: DIN B			210	-	-	209
	Clinical or Non-Clinical data only		$76,132				
	CLIN: SNDS (Supplement to a New Drug Submission)			300	233	272	286
	Chemistry & Manufacturing data only		$21,756				
	C&M ANDS (Abbreviated New Drug Submission)			180	-	180	180
	C&M: SNDS (Supplement to a New Drug Submission)			180	146	168	168
	C&M: DINB (Drug Identification Number)			210	153	192	206
	Comparative Studies Chemistry & Manufacturing data		$46,016				
	COMP C&M: SNDS (Supplement to a New Drug Submission)			180	179	177	179
	Labelling Only		$2,931				
	LABELLING ONLY: SNDS (Supplement to a New Drug Submission)			60	33	55	50
	Published Data		$18,041				
	PUBLISHED DATA: SNDS			300	177	140	291
	Administrative Submission		$303				
	ADMINISTRATIVE: NDS (New Drug Submission)			45	38	42	28
	ADMINISTRATIVE: DIN B (Drug Identification Number)			45	36	-	-
	Remission (processing fee applicable to all fee types)		$532	Per fee class/type	N/A	N/A	N/A

Appendix E – Service standards, fees and performance results for Medical Device Evaluation, Establishment Licences and Right to Sell

Source of information: Services standards: Canada Gazette, Vol. 148, No. 11 – March 15, 2014; Services fees: Health Canada Departmental Performance Reports for the fiscal years from 2011-12 to 2013-14

Medical Device Evaluation:
This category is more complex. With respect to evaluating medical devices, there are different fees and performance standards, depending on the Class of medical device. Fees increase, as does the length of time to evaluate a product, depending on the complexity of the product and the level of potential risk of that product. Thus, evaluating a Class II medical device has a lower user fee and a shorter performance standard than a Class IV medical device, which is defined as having more potential risk.

Performance:
Average time in calendar days to issue the first review decision (Review 1). Items that did not meet the performance standard are marked in *red*.

The *User Fees Act* requires a fee reduction equivalent to the unachieved performance where performance results are in excess of the service standard by more than 10% (to a maximum of 50% of the user fee). The reduced user fee applies from the day upon which the annual report for the fiscal year is tabled to the day upon which the next annual report is tabled.

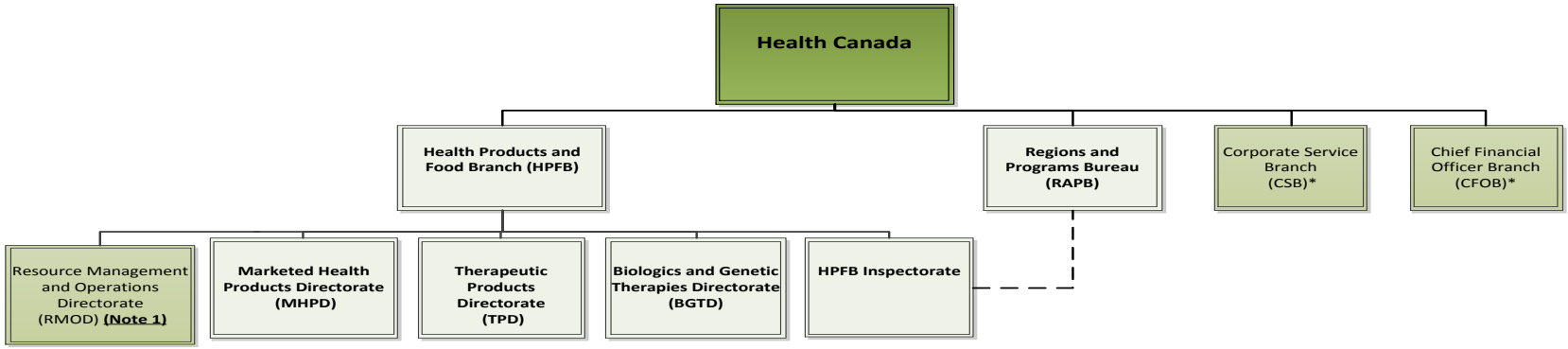
User Fees (Fee Lines)	Fee Class and Type	Fee as of April 1, 2014	New User-Fee Service Standards effective April 1, 2011 (days)	Performance Results (days)		
				2011-12	2012-13	2013-14
Medical Device – Evaluation (MDEVAL)	***Class II***					
	Class II New	$373	15	10.49	12.99	11
	Class III					
	Class III New	$5,361	60	45.02	51.46	53
	Class III Near Patient	$9,127	60	40.86	50.42	49
	Class III Manufacturing Amendment	$1,349	60	25.92	37.8	44
	Class III Significant Amendment	$5,021	60	43.25	52.14	53
	Class IV					
	Class IV New	$12,470	75	67.33	68.09	*78*
	Class IV Human-Animal Tissue	$11,633	75	70	67	62
	Class IV Manufacturing Amendment	$1,349	75	32.72	43.1	59
	Class IV Significant Amendment	$5,721	75	52.14	63.64	67
	Remission (processing fee applicable to all fee types)					
	Remission Fee	$55	Per fee class/type	N/A	N/A	N/A

Establishment Licences and Right to Sell:
These fees are charged for both medical devices and drugs. Establishment Licences allows industry to manufacture, distribute, import, wholesale or test regulated products in Canada. 'Right to Sell' allows industry to officially sell a regulated product in Canada. These performance standards are straightforward, with a single fee and a single performance standard for each product line and service.

User Fees (Fee Lines)	Fee Category and Type	Fee as of April 1, 2014	New User-Fee Service Standards effective April 1, 2011	Performance Results (days)		
				2011-12	2012-13	2013-14
Establishment Licensing						
Drug - Establishment Licences (DEL)	Multiple fees may be applicable, depending on type and size of manufacturer, importer or distributor. However, the service standard to issue a drug establishment licence is the same, regardless of the number of applicable fees.		250 calendar days to issue / renew licence	Met: Average number of days: 121	Met: Average Number of days: 183	Met: Average Number of days: 153
	Fee Category	Fee Type				Fee
	Fabrication of Drugs — Schedule 2	Basic fee				$16,397
		Each additional category				$4,108
		Dosage form classes				
		2 classes				$8,204
		3 classes				$16,397
		4 classes				$20,505
		5 classes				$24,600
		6 classes				$28,696
		Each additional class				$1,646
		Sterile dosage forms				$8,204
	Packing/Labelling of Drugs — Schedule 3	Basic fee				$10,963
		Each additional category				$2,739
		Dosage form classes				
		2 classes				$5,467
		3 or more classes				$8,204
	Importation and Distribution of Drugs — Schedule 4	Basic fee				$6,836
		Each additional category				$1,710
		Dosage form classes				
		2 classes				$3,419
		3 or more classes				$6,836
		Each fabricator				$1,646
		Each additional dosage form class for each fabricator				$829
	Distribution or Wholesaling	Distribution or wholesaling fee				$4,108
	Testing	Testing fee				$2,739
	Drug Analysis — Schedule 5	Vaccines				$27,327
		Drugs, not included in items 1, 6 and 9 of this Schedule, that are listed in Schedule D to the Food and Drugs Act 25				$10,932
		Drugs for human use that are prescription drugs, controlled drugs or narcotics				$8,204
		Drugs for human use, not included in any other item, for which a drug identification number has been assigned				$4,108
Dealer's licence	*Fees for the Examination of Dealer's Licence Applications*	Dealer's licence Service standard = 250 days to renew				$4,788
Medical Devices -	Medical Devices - Establishment Licences	$7,641	120 calendar days to issue / renew	Met. Average	Met: Average	Met: Average

User Fees (Fee Lines)	Fee Category and Type	Fee as of April 1, 2014	New User-Fee Service Standards effective April 1, 2011	Performance Results (days)		
				2011-12	2012-13	2013-14
Establishment Licences (MDEL)			licence	77 days	101 days	90 days
Right to Sell						
Drugs - Right to Sell (DRTS)	Drugs - Right to Sell	$1,084	120 calendar days to update the Drug Product Database following notification	Met: Average number of days: 9.1	Met: Average number of days = 7.1	Met: 100% within 120 days
Medical Devices - Right to Sell (MDRTS) * Class II, III or IV Medical Devices only	Fee- annual gross revenue of medical device sales is less than $20,000	$55	20 calendar days from deadline for receipt of annual notification to update the Medical Devices Active Licence Listing (MDALL) database	Met: 99.8% within 20 calendar days	Met: 99.9% within 20 Calendar days	Met: 99.9% within 20 Calendar days
	Fee - in any other case	$351				

Appendix F – Organizational chart for cost-recovery activities

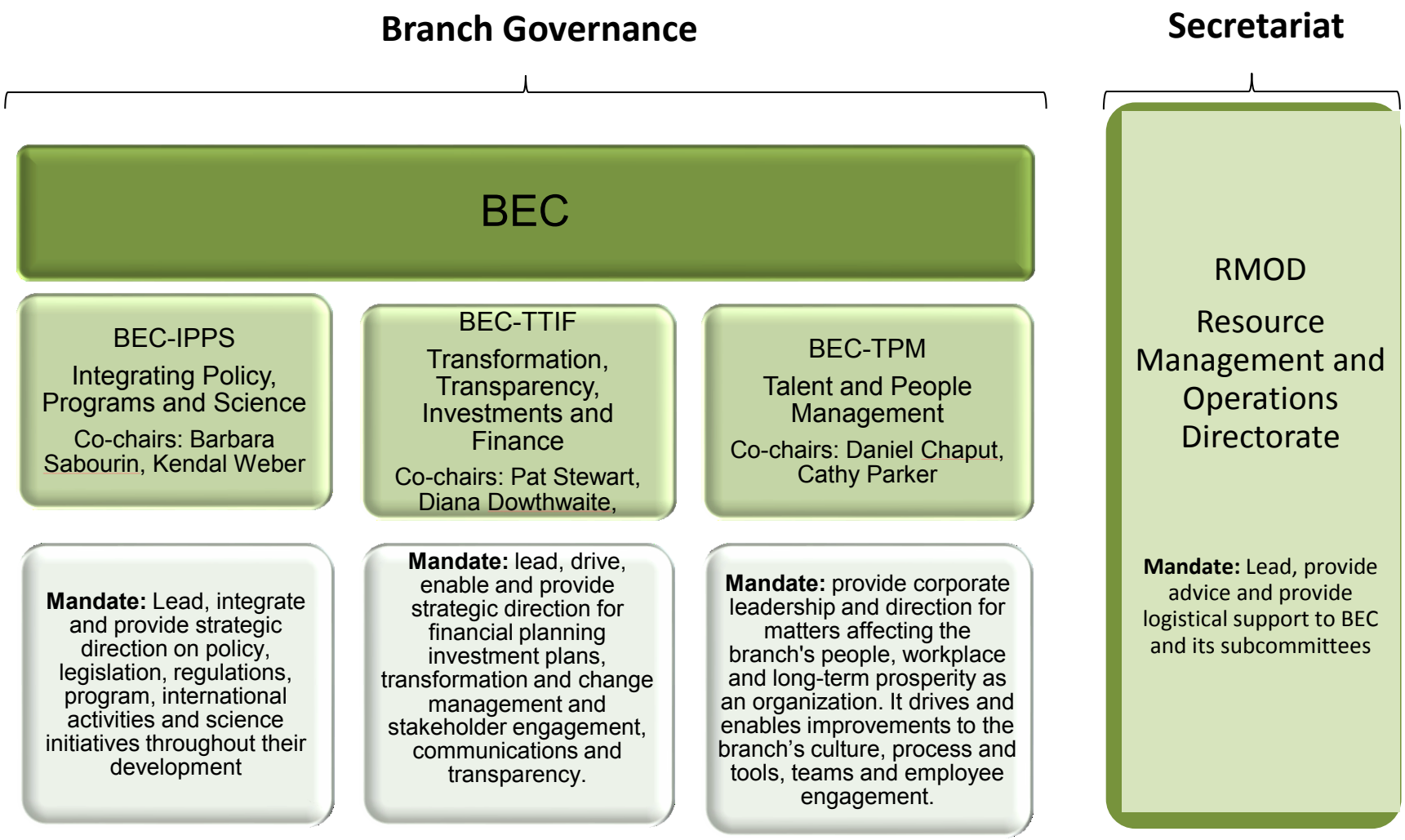


Direct involvement in cost-recovery activities.

* Provides functional support for cost-recovery activities (for example, HR, IT, finance).

Note 1: The RMOD is a horizontal directorate that provides branch-wide oversight, coordination and guidance on the consistent, efficient and effective management of operations and resources across the programs.

Appendix G – Governance structure



Appendix H – Allocation of user-fee revenues for 2013-14 by branch and fee line ($000s)

FEE LINE	HPFB	RAPB	CSB	CFOB	TOTAL	Employee Benefit Plan	GRAND TOTAL
Drug Evaluation - Pharmaceuticals	24,334	76	1,805	337	26,552	3,182	**29,734**
Drug Evaluation - Biologics	6,537	20	485	91	7,133	855	**7,988**
Medical Device Evaluation	5,150	16	380	71	5,617	669	**6,286**
Drug Establishment Licences	4,523	4,972	702	131	10,328	1,238	**11,566**
Medical Device Establishment Licenses	3,504	3,898	551	103	8,058	971	**9,027**
Drug Right-to-Sell	7,035	2,165	680	127	10,007	1,199	**11,206**
Medical Device Right to Sell	5,282	1,624	510	95	7,511	899	**8,410**
Total	**56,365**	**12,771**	**5,113**	**955**	**75,204**	**9,013**	**84,217**

Source: SAP data provided by Branch Senior Financial Officer (unaudited)