Charging for Services, Rights and Privileges within the Health Portfolio

May, 2000

Office of Revenue and Costing
Departmental Planning and Financial Administration Directorate
Corporate Services Branch

Health Canada

Preface

The past decade has witnessed dramatic changes in public expectations about fiscal responsibility in government. The impact of the federal government's Program Reviews is well known: a fundamental rethinking about government's role in providing services has been required. Efforts to meet concerns about why some services are delivered and how performance can be measured and improved may be found in government initiatives introducing charges for services, rights and privileges.

Charging for services, rights and privileges, or, "cost recovery", has become an integral feature of many programs under the authority of the Minister of Health, that is, within the "Health Portfolio". Central to these initiatives is the rationale that charging fees fosters greater accountability for the use of scarce government resources.

By charging for services, rights and privileges, direct users have an opportunity to decide if they do value the services, rights and privileges they are getting. In the context of today's exponential growth in health-related knowledge, technology, techniques and therapies, these charges can act as a natural check against spiralling costs and demands on programs.

Implementing cost recovery is not without challenges. For instance, achieving the goal of greater accountability for scarce government resources is difficult in many situations. In a competitive market where service alternatives exist and services can be responsive, service costs can be held to efficient and competitive levels. However, with regulatory programs imposing mandatory fees, a *de facto* monopoly exists, and market forces cannot make an impact. In these cases, consultative processes play a vital role in ensuring accountability that might otherwise be derived from market pressures.

The extensive consultations that have been undertaken to support Health Portfolio cost recovery initiatives have served to support greater accountability and increase understanding between government, clients and stakeholders. Many who have participated in these consultations have seen them as a key benefit of charges being introduced.

This document has been developed to provide a starting point for those interested in learning more about charging for services, rights and privileges within the Health Portfolio.

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It should be helpful for those participating in consultations and working with decision-makers inside and outside government in efforts to ensure that cost recovery initiatives contribute to the overall success of programs within the Health Portfolio.

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1. The Context for Charging for Services, Rights and Privileges within the Health Portfolio

1.1 Introduction

This document has been developed for those interested in learning about charging for services, rights and privileges by programs carried out with the authority of the Minister of Health ("the Health Portfolio").

The document provides

- background about charging for services, rights and privileges within the Health Portfolio
- the principles, procedures and processes that govern charging for services, rights and privileges
- summary profiles of programs charging for services, rights and privileges and those being developed.

The reader will find references throughout the text to web sites or telephone numbers for further details.

1.2 Background

Charging for services, rights or privileges, or, "cost recovery",has been a feature of many programs within the Health Portfolio for some time. Cost recovery was welcomed as a means of supplementing program budgets, meeting deficit challenges and increasing the efficient use and management of resources throughout the late 1980's and the early 1990's. Following the Federal Government's Program Review (I and II), Health Canada received approval to proceed with a number of new proposals.

During this same period, Treasury Board developed and refined its policy on charging user fees in an effort to assist federal departments and agencies in developing and managing the recovery of fees for services or for the market value of rights or privileges (e.g., licenses and permits to undertake regulated activities). The 1989 Treasury Board policy on "External User Charges for Goods, Services, Property, Rights and Privileges" was revised in 1997 as the "Cost Recovery and Charging Policy". This policy is being reviewed again during the year 2000.

The Treasury Board policy addresses key implementation issues: types of fees, required authorities, relationship of fees to costs, consultation and monitoring. The rationale for cost

recovery is:

- "to promote the efficient allocation of resources (i.e., to eliminate the excess demand that often exists with "free goods" by subjecting programs to a market test of supply and demand)

- to promote an equitable approach to financing government programs, mandatory or otherwise, by fairly charging clients or beneficiaries who benefit from services beyond those enjoyed by the general public. This may allow a greater share of general tax dollars to be devoted to activities that benefit the general taxpayer, or to reduce the debt. It may also facilitate improvements in the delivery of specific cost-recovered services

- to earn a fair return for the Canadian public for access to, or exploitation of publicly owned or controlled resources."

> For more information about this policy contact: Director, Planning and Projects, Treasury Board Secretariat: 957-0578, or, http://www.tbs-sct.gc.ca/Pubs_pol/opepubs/TB_H/siglist_e.html

1.3 Overview of Health Portfolio Cost Recovery Initiatives

All the cost recovery initiatives within the Health Portfolio serve to support programs to varying degrees: no programs at this time are fully cost recovered.

Many cost recovery initiatives within the Health Portfolio are tied to regulatory requirements. For example, regulations require that in order to have the right to market a drug in Canada, a Drug Identification Number (DIN) must be obtained. Fees are charged for obtaining and maintaining this number. Other cost recovery initiatives are not dependent on regulatory requirements. For example, fees are charged for obtaining a "Drug Export Certificate", a certificate that is not a mandatory requirement but which, for exporters, facilitates the sale of a licensed Canadian drug in other countries.

Cost recovery initiatives may currently be found within the following Health Portfolio programs:

- Therapeutics Products Program
- Environmental Health Program
- Pest Management Regulatory Program
- Occupational Health and Safety Program
- Medical Services Program
- Food (and Veterinary Drugs) Program
- Hazardous Materials Information Review Program.

Additional cost recovery initiatives are being developed within the Environmental Health Program, the Food Program, the International Business Development Program and the Business Development for Health Protection Branch Program.

1.4 Portfolio Support for Cost Recovery Initiatives

Each cost recovery initiative has been developed to support a particular Health Portfolio program and accordingly each initiative is unique in many ways. For example, the authority for charging fees for services varies from program to program (e.g., regulations, Ministerial authority, *Financial Administration Act*). Each program is also supported to different degrees by Appropriations-based funding, that is, funding from the Consolidated Revenue Fund (i.e., tax revenues) as approved by Parliament annually. As a result, each cost recovery initiative is managed within the context of the host program.

All the cost recovery initiatives are supported by Health Canada's Corporate Services Branch (CSB) to the extent required by each program. As part of CSB's Departmental Planning and Financial Administration Directorate's efforts to provide quality, cost effective services to Health Portfolio programs, the Office of Revenue and Costing has been established specifically to provide corporate support to cost recovery initiatives within the Health Portfolio. This Office provides assistance to Health Portfolio programs by developing and coordinating information sharing initiatives, assessing proposals and advising on cost recovery issues. This Office also serves as the department's primary contact on these issues with other federal departments and agencies.

During the mid-1990's, an Inter-Branch Cost Recovery Committee assisted programs in establishing systems and addressing operational challenges. This committee has been succeeded by the Health Portfolio Cost Recovery Committee ("the Committee") to work with the remaining horizontal issues and challenges within the Health Portfolio. The Committee is an action-oriented group of senior managers (i.e., equivalent to Director level or higher) with responsibilities for cost recovery initiatives within the Health Portfolio.

The Committee has been formed to provide a coordinating mechanism for information sharing and a forum for discussion and decision-making about cost recovery initiatives within the Health Portfolio. Specifically, the Committee's responsibilities include the consideration of:

- departmental, branch and agency policies concerning and/or affecting cost recovery
- portfolio-wide, horizontal, cost recovery management issues (including differences in approaches to management challenges)
- strategic considerations relating to the implementation of cost recovery program requirements
- opportunities for information sharing and training (e.g., Best Practices sessions)
- requirements for support from the Office of Revenue and Costing (CSB)

- effective liaisons with other federal departments.

The Committee maintains a link with the Departmental Executive Committee (DEC) and the Associate Deputy Minister. Members on the Committee, as senior managers, are in a position to support more effective and efficient communications within the management of the Health Portfolio and provide the Health Portfolio management with a direct link to cost recovery program management.

The Office of Revenue and Costing provides secretariat services to the Committee.

> For more information about the Health Portfolio Cost Recovery Committee or the Office of Revenue and Costing (CSB) contact: the Director of the Office of Revenue and Costing at 957-7324.

2. Principles, Procedures and Processes

2.1 Governing Principles

The principles governing cost recovery within the Health Portfolio are those set out in the Treasury Board Policy and those directing the Minister of Health to help the people of Canada maintain and improve their health. In addition, cost recovery within the Health Portfolio is also governed by the principles that cost recovery initiatives:

- do not compromise health and safety standards
- honour international trade agreements
- involve open, transparent consultations
- minimize the impact on Minister's legal liability
- seek opportunities to avoid and reduce costs of services where costs are recovered
- support the availability of regulated products or services.

2.2 Supporting Procedures and Processes

Cost recovery initiatives within the Health Portfolio have developed, or, are in the process of developing, procedures and processes to support the efficient management and effective delivery of cost recovery services. These are outlined below. Horizontal, Portfolio-wide efforts are also being developed by the Health Portfolio Cost Recovery Committee to improve and extend existing procedures and processes.

2.2.1 Open, Effective and Meaningful Consultations

The Health Portfolio is committed to supporting open, effective and meaningful consultations. Each program develops its own consultation processes to meet the needs of its particular group of clients and stakeholders. This is an ongoing process as each program develops a better understanding of the needs and concerns of clients and stakeholders.

2.2.2 Impact Assessment On Clients and Stakeholders

Cost recovery initiatives are subject to business impact analyses. These analyses involve

working with clients and stakeholders to address concerns unique to the sectors involved. The results are used in refining proposals before the formal comment stage required by the Canada Gazette, (Part 1) (where gazetting is required).

Cost recovery initiatives are also the subject of ongoing reviews. For example, the “Phase IV Review” of the Therapeutic Products Program (TPP) is undertaking a comprehensive impact assessment of the impact of the TPP’s fees on stakeholders, the health care sector and TPP itself.

2.2.3 Setting and Amending Fees

Fees are proposed and set by each program. In most cases, the setting of fees within the Health Portfolio involves the following steps:

- identification and initial policy analysis of potential user fees
- consultations with clients and stakeholders
- assessment of the potential impact of the fees
- preparation of a Business Plan (a formal proposal) for review by stakeholders and central agencies
- incorporation into regulations (where applicable)
- final approval, publication and implementation
- monitoring and reporting on the fees and making of further changes where appropriate.

2.2.4 Costing and Pricing Methodologies

Most of the Health Portfolio cost recovery activities are subject to traditional costing methodologies. These methodologies take into account the direct and indirect costs (e.g., overhead costs), service and program requirements.

Some programs such as the Therapeutics Products Program use activity-based costing to arrive at the costs associated with individual fees. For each fee, the costs associated with the individual activities undertaken in providing the service are identified and costed. Program activities of a general nature (e.g., planning, policy, development, administration) are costed and prorated to individual fee initiatives.

Pricing methodologies typically take into account the following factors:

- impact on clients

- impact on program mandates
- private versus public benefit
- nature of initiative and its pricing limits
- similarities to fees for similar services in other regulatory regimes or jurisdictions
- total funding sources and requirements for the program (e.g., costs, volumes, workload and related costing information)
- input from clients and stakeholders
- adjustments for special concerns (e.g., in cases where the fees may be prohibitively high (as for small firms or products for which there is a small demand), fees may be reduced according to a prescribed formula)
- other specific program requirements.

2.2.5 Dispute Resolution Processes

Each program area has established, or is in the process of establishing, a dispute resolution process of some kind. These processes provide opportunities for resolving disputes and may include informal discussions with program officials, use of a formal appeal process, appeal to the Minister or to the Treasury Board Secretariat.

3. Health Portfolio Cost Recovery Programs

3.1 Introduction

This section provides a summary overview of the cost recovery initiatives underway within the Health Portfolio. The initiatives described in this section form integral components of the following programs:

- Therapeutics Products Program
- Environmental Health Program
- Pest Management Regulatory Program
- Occupational Health and Safety Program
- Medical Services Program
- Food Program
- Veterinary Drugs Program
- Hazardous Materials Information Review Program.

This section does not provide specific information on the fees charged by programs. However, this document does provide telephone numbers for contact with program managers and references to web sites that can supply details about program requirements. *Note* that most programs provide for fee reductions in specified circumstances (e.g., low volume sales or small businesses) and the details of these circumstances may also be determined by direct reference to the program's web site.

3.2 Therapeutics Products Program

3.2.1 Program Objective

The Therapeutic Products Program (TPP) is the national regulatory authority for human drugs and medical devices. The program's objective is to ensure the safety, effectiveness, and quality of drugs, medical devices, and other therapeutic products available to Canadians.

3.2.2 Legislative and Regulatory Authorities

The *Financial Administration Act* (including the *Authority to Sell Drugs Fees Regulations, Drug Evaluation Fee Regulations, Fees in Respect of Medical Devices Regulations, Drug Establishment Licensing Fees Regulations, Licensed Dealers for Controlled Drugs and Narcotics Fees Regulations*), the *Food and Drugs Act*, the *Controlled Drugs and Substances Act.*

3.2.3 Profile of Stakeholders

The stakeholders include:

- industry associations
- consumer associations
- professional associations
- health issues associations
- academics.

3.3.3 Features of Cost Recovery Initiatives

TPP Cost Recovery for Drugs

Cost recovery for drugs has five components – three that are associated with mandatory (i.e., required by regulation) activities, and two that are non-mandatory (i.e., not required by regulations) and are a direct service to industry. (These programs are described below in the order in which they were implemented.)

- **Authority to Sell Drugs Fees (mandatory)**

This fee was implemented January 1, 1995. It is an annual fee for the maintenance of the right to market a drug in Canada, represented by the holding of a Drug Identification Number (DIN). A DIN is obtained as the result of a successful submission to the TPP's drug evaluation activities (see below) and fees are paid by the company/manufacturer on record as holding the DIN.

The TPP activities specific to the "Authority to Sell Drugs" are: the maintenance of information on drug products authorized to be marketed in Canada; post-market monitoring; and product-related investigations (e.g*.,* resulting from trade or consumer complaints, Customs surveillance, and laboratory analysis).

- **Drug Submission Evaluation Fees (mandatory)**

These fees were implemented September 1, 1995 and are charged to evaluate documentation submitted by a manufacturer demonstrating the safety, efficacy and quality of a drug product for specific conditions of use. If accepted, a DIN, and in most cases a Notice of Compliance(NOC) are issued for the drug product. There are four types of submissions:

- Type I – New Drugs Submissions (NDS)
- Type II – Supplement to a New Drug Submission (SNDS)
- Type III – Abbreviated New Drug Submission (ANDS) or Supplement to an Abbreviated New Drug Submission (SANDS)
- Type IV – Drug Identification Number (DIN).

The fees pay for the TPP activities specific to the evaluation of submissions as required by the Regulations under the *Food and Drug Act,* plus a portion of indirect Program activities (e.g. policy development, planning, administration). Note: manufacturers are paying for the review of their submissions. This may or may not mean approval, depending upon the quality of the information in the submission. A sponsor must pay the fee regardless of whether the product is approved or not. Fees are paid by all companies/manufacturers who are seeking licensing of human drug products, although fee reductions and exceptions are available under specific conditions.

- **Drug Master File Fees**

These fees were implemented January 1, 1996 for the TPP activities relating to a Drug Master File (DMF) (e.g., registration, letters of authorization). The DMF contains proprietary information about specific components (e.g., packaging materials, colourants, flavours) used in the manufacturing processing and packaging of a drug. The TPP needs to know this information to ensure acceptability of the components. However, companies who use the components in their products do not necessarily have access to this information.

The fees are paid by DMF owners applying for registration and/or authorizing release of information through a Letter of Access. Payments are made at the time of a DMF registration (original filing only), and whenever the TPP is asked to process a Letter Of Access.

- **Drug Export Certificate Fees**

These fees were implemented May 1, 1996 and are for a certificate provided by TPP to an exporter to facilitate the sale of a licensed Canadian drug in another country. The certificate is both product-specific and specific to the importing country.

The fees pay for the TPP activities relating to the issuance of a Drug Export Certificate, in a format defined by the World Health Organization (WHO). The certificate provides information on:

- the status of a specific pharmaceutical product
- the Good Manufacturing Practice (GMP) status of the applicant.

C Drug Establishment Licensing Fees

These were implemented January 1, 1998. These are annual fees for a licence – required by fabricators, packagers, importers, distributors, wholesalers (scheduled drugs only) and testers – that certify the type of operations and products authorized to be handled by an establishment. The issuance of a licence is dependent on meeting Good Manufacturing Practice (GMP) requirements under the *Food and Drug Regulations* and, where applicable, the security requirements for narcotics and controlled substances under the *Controlled Drugs and Substances Act.*

The TPP activities which support Drug Establishment Licensing are:

- inspection/assessments conducted to ensure that drugs are fabricated, packaged, labelled, imported, distributed, wholesaled and tested in compliance with the GMP Regulations
- product analyses undertaken to assess the adequacy of an establishment's quality control department
- where applicable, inspections to ensure compliance with security requirements under the Regulations to the *Controlled Drugs and Substances Act.*

The following types of establishments require a license:

- a fabricator, packager/labeller, or importer of drugs
- a wholesaler of scheduled drugs
- a drug testing laboratory
- a distributor of a drug who also holds the DIN
- a distributor of a drug listed in Schedule C, D or G to the *Food and Drugs Act* or Schedule F under the Regulations to the *Food and Drugs Act* who does not hold the DIN for the drug
- a distributor of a narcotic as defined in Section 2 of the *Controlled Drugs and Substances Act,* who does not hold the DIN for the drug or narcotic.

Establishments who deal exclusively with natural health (e.g., herbal, vitamin, homeopathic) products are currently exempt.

C TPP Cost Recovery for Medical Devices

Cost recovery for medical devices has three components relating to the manufacture, licensing and marketing of medical devices. These are:

- **Medical Device Licence Application Fees**

These fees were implemented September 1, 1998 for a licence that authorizes a manufacturer to sell a Class II, III or IV medical device in Canada. Fees support TPP's activities to evaluate the application by a manufacturer to sell a Class II, III or IV medical device in Canada.

- **Fees for the Right to Sell a Licensed Medical Device**

These fees were implemented November 1, 1999 and are for renewal of the license to sell a Class II, III or IV medical device in Canada. The annual fees cover a portion of costs related to TPP's medical device product post-market monitoring activities.

- **Medical Device Establishment Licence Fees**

These fees were implemented January 1, 2000 for the issuance of a licence that authorizes companies to import or distribute all classes of medical devices. This licence is also required for manufacturers of Class I medical devices who do not sell through a licensed Canadian importer or distributor.

The fee covers a portion of the costs relating to the TPP's medical device establishment post-market monitoring activities and is paid by importers/distributors of Classes I, II, III and IV medical devices and manufacturers of Class I devices who do not sell through a licensed Canadian importer or distributor. Fees apply equally to foreign and domestic establishments.

For more information about the Therapeutics Products Program contact: Manager, Office of Management Services, Therapeutics Products Program, 957-8195, or,
www.hc-sc.gc.ca/hpb-dgps/therapeut.htm/eng/index.html

3.3. Environmental Health Program

3.3.1 Program Objective

The objective of the program is to contribute to sustainable development, improve the safety and safe use of products and reduce health risks by identifying, assessing and managing the risks and benefits in natural and human-made environments.

3.3.2 Legislative, Regulatory and Other Authorities

For the dosimetry program: the *Financial Administration Act* (including *Dosimetry Services Fees Regulations*). For the issuing of food export certificates: the authority is the "Minister's right to contract". For the New Substances Notification Program: the governing regulations are the *New Substances Notification Regulations for Chemicals and Polymers* pursuant to the *Canadian Environmental Protection Act* (CEPA, 1999) and with respect to the setting of fees, the *Financial Administration Act* (or the *Department of Health Act*).

3.3.3 Profile of Stakeholders

The stakeholders include:

- organizations whose workers use radioactive material and/or radiation emitting devices (e.g., X-rays). The organizations include major hospital corporations with nuclear medicine departments, industrial facilities, dental offices and laboratories, private clinics, uranium mining and refining, nuclear power utilities, and research and educational facilities.
- Canadian food producers, primarily exporters of dairy products
- manufacturers, importers, exporters of cosmetics, chemicals, polymers or biotechnology products.

3.3.4 Features of Cost Recovery Initiatives

C National Dosimetry Services (NDS)

NDS provides personal lifelong occupational monitoring for ionizing radiation to about 100,000 individual Canadian workers. This involves issuing and evaluating personal measuring devices (or dosimeters) to determine exposure to ionizing radiation. In 1994, NDS transformed itself from a funded government program to a self reliant, cost recovered organization. NDS supports its business through revenues earned from the sale of dosimetry products and services to the private and public sectors in Canada. NDS is also in direct competition with national and international commercial dosimetry providers within Canada.

c Food Radiation Assessment for Canadian Food Exporters

Following the Chernobyl incident, some countries and foreign banks (who issue letters of credit) require food certificates attesting to the fact that the food being exported is free of harmful levels of radioactivity and fit for human consumption. The Radiation Protection Branch works in partnership with the Canadian Food Inspection Agency in order to streamline this service.

c New Substances Notification Program

Health Canada has responsibilities for assessing and determining new substances in terms of potential risks to human health. (Environment Canada assess potential environmental risks.)

c Label Review Service

Health Canada's Product Safety Program provides this optional service to assist traders in developing (and reviewing drafts of) labels for regulated and non-regulated products before they are applied to containers of consumer chemical products.

A cost recovery initiative is also being considered for "Cosmetic Annual Registration" (see page 30).

For more information about the Environmental Health Program contact: Director Bureau of Strategic Planning and Business Operations, Environmental Health Program, or, http://www.hc-sc.gc.ca/ehp/ehd/

3.4 Pest Management Regulatory Program

3.4.1 Overview of Program's Objective

The objective of this program is to protect human health and the environment by minimizing the risks associated with pest control products, while enabling access to pest management tools, namely, these products and sustainable pest management strategies.

The federal government's pest management regulatory program is managed by the Pest Management Regulatory Agency (PMRA). PMRA was established within Health Canada on April 1, 1995 with a mandate to protect human health and the environment while supporting the competitiveness of agriculture, forestry, other resource sectors and manufacturing. In April 1997, the *Pest Control Products Fees Regulations* came into effect replacing the previous fees that were in effect.

3.4.2 Legislative and Regulatory Authorities

The *Pest Control Products Act, Regulations Prescribing the Fees to Be Paid for a Pest Control Product Application Examination Services Provided by or on Behalf of Her Majesty in Right of Canada, for a Right or Privilege to Manufacture or Sell a Pest Control Product in Canada and for Establishing a Maximum Residue Limit in Relation to a Pest Control Product (Pest Control Products Fees Regulations)* and the *Financial Administration Act*.

3.4.3 Profile of Stakeholders

PMRA has worked with stakeholders to develop its cost recovery system. Stakeholders include:

- health interest groups
- manufacturers
- grower groups
- user groups
- research community
- environmental groups
- consumer groups
- other government departments.

3.4.4 Features of Cost Recovery Initiatives

- **Registration of Pest Control Products**
  - **Application fee**

This fee is the sum of different fees which are charged for the various data components making up a submission. These different fees are based on the amount of effort required to examine an average data package. For major submissions, fees are payable as follows:

- 10% at time of application
- 25% when the application has been accepted for preliminary review for deficiencies; and
- 65% when the application has been accepted for evaluation.

Applicants pay for the examination of their submissions. This may or may not result in an approval. An applicant must pay the fee regardless of whether the product is approved or not.

  - **Maintenance fee**

This fee is charged annually for the right or privilege to manufacture or sell, for use in Canada, a registered pest control product, represented by the holding of a Pest Control Product (PCP) number. A PCP number is obtained as a result of a successful submission to PMRA. The fee for each product is payable by the registrant on record as holding the registration on April 1st of each fiscal year.

> For more information about the Pest Management Program contact: Director Management Planning and Coordination Division, Pest Management Regulatory Agency, 736-3411, or, http://www.hc-sc.gc.ca/pmra-arla/gpro-e.html

3.5 Occupational Health and Safety Program

3.5.1 Program Objective

The program objective is to provide a broad range of direct occupational and public health and safety services and advice to all levels of government, federally regulated organizations and industries and non-government organizations, to continue to work with other parts of Health Canada to protect the health of the Canadian population from the ingress of specific diseases and to protect the health of visiting Very Important Persons (VIPs) in Canada.

The occupational health and safety program is managed by the Occupational Health and Safety Agency (OHSA). OHSA was established as a provisional Special Operating Agency (SOA) in 1996 to provide services in four main areas: occupational health and safety (OHS; includes employee assistance services and traumatic stress management), quarantine, public health and VIP services. It is currently seeking full SOA status.

3.5.2 Legislative, Regulatory and Other Authorities

The *Department of Health Act*, Memoranda of Understanding (MOUs) with participating departments and agencies, World Health Organization international agreement.

3.5.3 Profile of Stakeholders

Stakeholders (and potential client sectors) include:

- federal departments and agencies
- federally regulated industries (e.g., cruise ship industry, airlines)
- Very Important Persons (federal departments and agencies)
- inter-provincial common carriers (e.g., ferry companies)
- local airport authorities
- food operators inside terminals
- facilities and services inside federal parks
- other levels of government
- non governmental organizations
- universities and publically funded educational institutions.

3.5.4 Features of Cost Recovery Initiatives

- **Occupational and Safety Services**

Currently, the Agency is funded to provide mandatory occupational and safety services to other

government departments. OHSA is proposing to offer these services on a cost recovery basis. (Government departments will have the option of obtaining these services from other service providers.)

- **Employee Assistance Services (EAS)**

This program involves coordinating services for a number of departments through a cost-shared brokerage arrangement. This allows for lower costs through economies of scale (especially in areas with small numbers of federal public servants) as well as improved gathering of statistics and quality assurance.

This program is operated on an incremental cost recovery basis on the basis of MOUs with participating departments. As in the case of other occupational, health and safety services, a customer base outside of the traditional federal customer group has been established. Full costing is carried out for services delivered to clients outside the federal government.

- **Quarantine Services**

In the fall of 1995, quarantine services commenced cost recovery for services relating to deratting certificates (i.e., specialized inspection of sea-going vessels for the presence of disease-carrying rats arriving at Canadian ports of entry).

- **Cruise Ship Inspection Program**

This program operates under the authority of the Department of Health Act. OHSA began recovering costs associated with the Cruise Ship Inspection Program on April 1, 1998.

Inspections are provided pursuant to a World Health Organization international agreement to ensure the protection of the traveling public and citizens in the ports of call. This voluntary compliance program was set up after extensive consultation with industry, with three major cruise ship associations representing cruise ships sailing in Canadian waters.

As well, the Agency is working closely with U.S. providers of the service to harmonize the programs and reduce the burden on cruise lines where there are differing sanitary requirements and overlapping inspection timetables.

- **Very Important Persons (VIP) Services Program**

This program supports the Department of Foreign Affairs and International Trade, Secretary of State and Heritage Canada and the health concerns of official dignitaries visiting Canada. OHSA coordinates the development of required health care plans, including the inspection of food preparations and the preparedness of medical and hospital facilities. All costs related to VIPs, domestic or foreign, are recovered from the appropriate department.

- **Common Carrier Food Inspection Services**

The cost recovery program for air flight kitchens is targeted to begin in 2000-2001. This is not expected to be a significantly growing source of revenue. Other public service health services, such as food inspections in airports, will provide small amounts of additional revenue.

For more information about the Occupational Health and Safety Program contact: Finance Manager, Occupational Health and Safety Agency, or, http://www.hc-sc.gc.ca/ohsa/nehsi.htm

3.6 Medical Services Program

3.6.1 Program Objectives

The objectives of the program are twofold. The first is the recoveries from the Provincial Insurance Plans for out-patient and in-patient services provided in hospitals owned by Health Canada. The second is to supply program coordination and functional supervision services as well as drugs and medical supplies to First Nations communities. In this way, Health Canada assists First Nations communities and peoples in addressing health inequities and disease threats, and in attaining a level of health comparable to that of other Canadians by ensuring the availability of, or access to, health services and supplies to Registered First Nations and Inuit.

3.6.2 Legislative, Regulatory and Other Authorities

The authorities for the hospital services is the *Canada Health Act, 1984* (replacing the *Hospital Insurance and Diagnostic Act*) which transferred responsibilities for all hospitalization costs to the provinces and territories, including the costs incurred by the federal government, and the Treasury Board decision # 820933 (December 16, 1993).

The authority to permit the sale of goods and services to First Nations communities is Treasury Board decision # 824000 (April 18, 1996).

3.6.3 Profile of Stakeholders

The stakeholders are:

- (for the hospital services) the provinces where the hospitals are located, Workers' Compensation Boards and individual non-residents of Canada
- (for the health services and sale of drugs and supplies to First Nations communities) the First Nations communities.

3.6.4 Features of Cost Recovery Initiatives

Provision of Hospital Services

Hospital services are provided to in-patients and out-patients in hospitals owned by Health Canada (on an optional basis).

- **(Optional) Health Services**

Health services (coordination and functional supervision services) and the sale of drugs and medical supplies to the First Nations communities are supplied on an optional basis.

> For more information about the Medical Services Program contact:
> Medical Services Branch at
> http://www.hc-sc.gc.ca/msb/msb_e.htm

3.7 Food Program

3.7.1 Program Objective

The objective of the Food Program is to protect and improve the health of the people of Canada through science-based policies and programs related to safe and nutritious food.

3.7.2 Legislative and Regulatory Authorities

The legislative and regulatory authorities are *Department of Health Act* and the *Financial Administration Act*, the *Food and Drugs Act* and *Food and Drug Regulations*.

3.7.3 Profile of Stakeholders

The stakeholders are:

- the food industry and related associations
- nutrition groups and consumer groups
- central agencies
- Canadian Food Inspection Agency (CFIA).

3.7.4 Features of Cost Recovery Initiatives

The primary cost recovery initiative of the Food Program involves the Bureau of Veterinary Drugs (see following section 3.8). Cost recovery is also being considered in additional areas (see page 30).

For more information about the Food Program contact: Director Policy and Planning Food Directorate, Food Program, 941-1083, or, http://www.hc-sc.gc.ca/food-aliment/english/index.html

3.8 Veterinary Drugs Program

3.8.1 Overview of Program's Objective

The Bureau of Veterinary Drugs (BVD) is responsible for reviewing and approving veterinary drugs. These products help to meet the needs of Canadian animal agriculture, the needs of Canadians for a safe, wholesome food supply and the needs of Canada's companion animal population.

3.8.2 Legislative and Regulatory Authorities

The legal authorities are the *Financial Administration Act* and the *Food and Drugs Act* and *Food and Drug Regulations*, in particular the *Veterinary Drug Evaluation Fees Regulations.*

3.8.3 Profile of Stakeholders

The stakeholders include:

- veterinarians
- livestock producers, companion animal owners
- veterinary drug manufacturers, notably the Canadian Animal Health Institute (CAHI) which represents companies that develop and manufacture pharmaceuticals, biologicals, feed additives and animal pesticides used in agriculture and veterinary medicine.

3.8.4 Features of Cost Recovery Initiatives

The Bureau of Veterinary Drugs reviews data submitted by manufacturers to ensure compliance with safety and efficacy standards and manufacturing and product labelling requirements as set out in the *Food and Drug Regulations.* The *Veterinary Drug Evaluation Fees Regulations* came into effect on April 6, 1996.

Fees are charged for the review of:

- new drug submission
- supplement to a new drug submission
- abbreviated new drug submission (or supplement to an abbreviated new drug submission)
- Drug Identification Number (DIN) application
- preclinical (investigational) new drug submission
- experimental studies certificate application

- emergency drug release
- notifiable change or protocol review.

For more information about the Veterinary Drugs Program contact: Director Policy and Planning Food Directorate, Food Program acting as liaison for the Veterinary Drugs Program, 941-1083, or,
http://www.hc-sc.gc.ca/food-aliment/english/veterinary_drugs/

3.9 Hazardous Materials Information Review Commission

3.9.1 Overview of Program Objective

The objective of this program is to provide a mechanism for industry to protect the identity and concentration of trade secret ingredients in controlled products in use at Canadian workplaces, while at the same time ensuring that the Material Safety Data Sheets (MSDS) with those controlled products (which are the subject of the claim for exemption) provide accurate health and safety information.

3.9.2 Legislative and Regulatory Authorities

The *Hazardous Products Act*, the *Controlled Products Regulations*, the *Hazardous Materials Information Review Act*, the *Hazardous Material Information Review Regulations*, the *Hazardous Materials Information Review Act Appeal Board Procedures Regulations,* and the provincial and territorial occupational safety and health legislation and regulations.

3.9.3 Profile of Stakeholders

The Hazardous Materials Information Review Commission (HMIRC) was created following significant tripartite consultation with labour, industry and other government departments, both federal and provincial. Its stakeholders include:

- chemical manufacturers and formulators
- chemical importers and distributors
- employers
- user groups (labour)
- federal and provincial occupational health and safety professionals
- other government departments**.**

3.9.4 Features of Cost Recovery Initiatives

HMIRC was created as an independent agency in 1987. HMIRC administers the trade secret mechanism within Canada's Workplace Hazardous Materials Information Review System (WHMIS) as an arm's length administrative law tribunal charged with carrying out a multi-faceted mandate.

WHMIS (and supporting legislation) does not require suppliers to register their controlled products before selling them in Canada, providing that the identity and concentration of all of the hazardous ingredients in the controlled products above prescribed cut-off concentrations have been disclosed on the MSDS which accompanies each controlled product and must be available at the workplace. Registration prior to sale is required when exemption from full disclosure is requested by suppliers or employers.

- **Trade Secret Exemption Registration and Registry Number Issuance**

A supplier (defined as a person who is a manufacturer, processor or packager of a controlled product or a person who, in the course of business, imports or sells a controlled products) or, under some circumstances, an employer, can apply to HMIRC for exemption from disclosure where they determine that they would benefit from keeping the identity or concentration of certain hazardous ingredients confidential or decide that they wish to keep the identity of a toxicological study confidential.

The fee schedule for registration of a claim for exemption forms part of the *Hazardous Materials Information Review Regulations* and provides for a base fee for each controlled product plus an ingredient fee for each hazardous ingredient in the controlled product(s).

There is a minimum base fee covering a submission for a single controlled product containing only one hazardous ingredient. For submissions consisting of grouped claims, where there is some commonality of composition or end-use purpose, the applicable fee rises on a prescribed per product basis. In each case, an additional fee per distinct hazardous ingredient is applied and computed on the basis of each hazardous ingredient in the controlled product being subject to the fee (includes both disclosed hazardous ingredients and trade secret hazardous ingredients).

Issuance of a registry number occurs once the claimant has submitted a properly completed FORM 1 providing certain information prescribed in the *Hazardous Materials Information Review Regulations*. Initial issuance of the registry number is not dependent on the issuance of a decision on the validity of the claim nor is it dependent on the completion of the health and safety review or decision with respect to the compliance of the material safety data sheet.

As noted below, only one fee applies to the submission of a claim for exemption and this fee is collected at the time of registration of the claim and issuance of the Registry Number. This fee covers the review of submitted information on the basis of which HMIRC issues decisions on the validity of claims for exemption using a prescribed regulatory criteria.

The initial fee also covers the Review of Material Safety Data Sheets and Labels. HMIRC evaluates any unpublished documentation supplied by the claimant and reviews public literature databases to determine the nature and extent of health and safety information which must be disclosed on the material safety data sheet with respect to the disclosed hazardous ingredients and the trade secret hazardous ingredients.

Decisions are issued on the compliance of each MSDS which is the subject of a claim for exemption and Orders are issued with respect to items of non-compliance.

- **filing a statement of appeal**

HMIRC must convene independent, tripartite boards to hear appeals from claimants or affected parties on decisions and orders issued by HMIRC. The procedures for the convening of an

Appeal Board are outlined in the *Hazardous Materials Information Review Act Appeal Board Procedures Regulations*. Each statement of appeal must be accompanied by a fee.

For more information about the Hazardous Materials Information Review Commission, contact Vice-President, Corporate Services and Adjudication, Hazardous Materials Information Review Commission 993-4472 or http://www.hmirc-ccrmd.gc.ca/0001_e.htm

4. Health Portfolio Cost Recovery Initiatives Under Development

4.1 Introduction

This section provides descriptions of programs/initiatives that are under development at this time. These include the cost recovery initiatives within the following programs:

- Environmental Health Program
- Food Program
- International Business Development Initiative
- Business Development for Health Protection Branch Program.

4.2 *Additions to* the Environmental Health Program

Cost recovery is also being considered for the following:

- **Cosmetic Annual Registration**

Manufacturers and importers of cosmetics will undergo an annual registration of all ingredients they use in cosmetics and the cosmetic categories in which these ingredients are used. Annual registration will allow these companies to sell cosmetics in Canada.

4.3 *Additions to* the Food Program

Cost recovery is also being considered in the following areas of the Food Program:

- **Mandatory submissions**

Mandatory submissions from industry for food additives, novel foods, infant formula and irradiated foods.

- **Voluntary submissions**

Voluntary submissions from industry for food packaging materials and incidental additives.

4.4 International Business Development Initiative

4.4.1 Overview of the Objectives

Health Canada's International Business Development Division will seek to promote and export Canadian health expertise throughout the world. Ultimately, therefore, the objectives of the initiative is to support Health Canada, other government departments, the provinces and territories, non-governmental organizations and the private sector in offering their expertise in health management, governance and policy services and regulation to world markets.

4.4.2 Legislative, Regulatory and Other Authorities

The *Department of Health Act* and the *Financial Administration Act*.

4.4.3 Profile of Stakeholders

The stakeholders (and potential clients) include:

- private sector
- industry organizations (e.g., pharmaceutical associations, health services, hospital associations)
- non-governmental organizations (e.g., medical/nurses' associations, Canadian Society for International Health)
- international development banks (e.g., World Bank, Inter-American Development Bank)
- international development agencies (e.g., Canadian International Development Agency)
- aboriginal communities
- provinces and territories

4.4.4 Features of Cost Recovery Initiatives

This initiative is being designed to respond to international demand for Canadian Health expertise. Health systems development, reform and financing, HIV/AIDS, health protection and promotion (i.e., tobacco), occupational health, youth and aboriginal health, evidence-based medicine and reviews of national health expenditures are only some examples of Canadian expertise where there is demonstrated international demand and which the IBDD will seek to promote abroad. To that end, some cost recovery is contemplated.

For more information about this initiative contact: Senior Director, International Business

Development Division, 941-3335.

4.5 Business Development for Health Protection Branch Program

4.5.1 Program Objective

The objective of the program is to develop business opportunities for the Health Protection Branch (HPB). This involves:

- obtaining a reasonable financial return from costs incurred by HPB in the development of the intellectual property needed by HPB to meet its objectives but which also has a commercial value
- promoting the transfer of HBP technologies to a variety of groups including other levels of government, NGOs, and the private sector where applicable
- managing and protecting HPB intellectual property.

4.5.2 Legislative, Regulatory and Other Authorities

The *Public Servants Inventions Act*.

4.5.3 Profile of Stakeholders

The stakeholders are:

- private companies in health care industry
- public/private health care providers
- pharmaceutical companies
- food industry
- other levels of government
- non governmental organizations

4.5.4 Features of Cost Recovery Initiatives

The Business Development Office initiative is working to establish conditions under which the payment of royalties arising from Health Canada technologies can be used to offset costs of developing technologies and sustain funding for additional research without incurring a decrease in the existing Program A-Base.

For more information about this program, contact: Director Special Projects, Business Development for Health Protection Branch Program, 941-7290

5. Additional References

Treasury Board: Cost Recovery and Charging Policy

Cost Recovery in the Therapeutic Products Programme: An Overview

ESTIMATES: Health Canada: Performance Report (For the period ending March 31, 1998)