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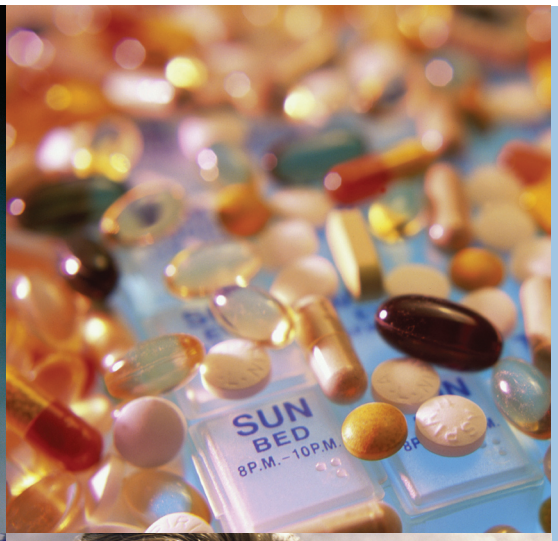
Health Products and Food Branch

2007 Blueprint for Renewal II

Modernizing Canada's Regulatory System for Health Products and Food



Canada

Health Products and Food Branch

2007

Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

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Message from the Assistant Deputy Minister

Neil Yeates
Assistant Deputy Minister
Health Products and Food Branch
Health Canada

I am pleased to present *Blueprint for Renewal II: Modernizing Canada's Regulatory System for Health Products and Food,* which builds on the original policy framework of the Blueprint.

In October 2006, Health Canada's Health Products and Food Branch (HPFB) released its Blueprint for Renewal plan, a major initiative aimed at modernizing Canada's regulatory system for health products and food. The Blueprint presented the vision and objectives for the renewal of our regulatory system, as well as proposed actions for moving forward.

From October to December 2006, HPFB consulted stakeholders and the general public on the Blueprint plan. This included a series of discussion sessions across Canada, as well as an electronic consultation.

We received strong support from Canadians on the case for renewal and orientations in the Blueprint. Constructive feedback from the consultations helped inform the development and implementation of our plan. We committed to not only prepare reports of what we have heard during the consultations, but also to incorporate this input into a revised version of the Blueprint.

Blueprint II fulfills this commitment. It offers a more comprehensive articulation of our action plan and how we will concretely move forward to design a regulatory system that will further protect the health and safety of Canadians.

Part 1 presents our case for renewal and revised framework, which reflects the views expressed by stakeholders in fall 2006.

Part 2 details the planned activities related to the various objectives of the Blueprint. Part 3 discusses next steps for implementing the activities, including how we will continue to involve the public and stakeholders throughout the various phases of this initiative and how we will report our results.

The initiatives presented in the Blueprint are part of a broader HPFB Strategic Plan for 2007-12, released at the same time as this report. Together, these two documents provide a clear roadmap for the future of our organization.

Blueprint for Renewal II* and *2007-12 Strategic Plan

Blueprint II, the original discussion document and reports from the fall 2006 consultations are available at www.healthcanada.gc.ca/hpfb-blueprint.

Our 2007-12 Strategic Plan is available at www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/index_e.html.

Part 1–The Case for Renewal and the Blueprint Framework

Why change our regulatory system?

Since 1953, the federal government's role and responsibilities for health products and food safety have been primarily defined through the *Food and Drugs Act*. The regulatory approaches in the Act and its regulations were designed to meet the challenges of the day—in fact, the Act was largely intended to be a consumer protection statute.

However, many things have changed since the 1950s, including the view of Canadians on the role of the government in regulation, particularly with respect to product safety, as well as the government's understanding of the value that the regulatory authority provides in advancing important public policy goals, including health policy goals. While Health Canada continues to be respected internationally as a modern regulator, the need to look to the future and the ongoing sustainability of the system is compelling, and the time to do so is now.

Key challenges. Health Canada has identified five major challenges that must be addressed to ensure continued, timely access by Canadians to safe and effective health products and a safe and nutritious food supply:

- an outdated regulatory toolkit that is increasingly limited and inflexible in responding to today's health products and food environment;
- the regulatory system's current incapacity to consider a given product through its entire life cycle, from discovery through to examining the "real-world" benefits and risks of a health product or a food on the market;
- the impact of social and economic changes, such as accelerating scientific and technological advances, the rise of transborder health and environmental threats, and a more informed and engaged citizenry;
- a regulatory system that currently works in isolation from the activities and policies at the research and development stage, and those of the broader health care system; and
- a regulatory system with insufficient resources for long-term efficiency and sustainability.

What we heard from stakeholders

In October 2006, the Health Products and Food Branch (HPFB) released its discussion document, *Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food,* which outlined a vision and plan for modernizing the regulatory system for health products and food. The document builds on significant progress we made over the last few years to improve the system's efficiency, safety and transparency. For more information on key achievements of the Branch over the past few years, please refer to the Progress Report on the 2004-07 Strategic Plan at www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/index_e.html.

At the same time, HPFB launched a series of consultations to seek the views of stakeholders on the Blueprint. In November 2006, seven regional consultation sessions were held across Canada with stakeholders, and an electronic consultation on the Blueprint took place from October 26 to December 6, 2006. Reports from these two consultations are available at www.healthcanada.gc.ca/hpfb-blueprint.

Participants expressed strong support for renewing the Branch's regulatory approach, as well as with the Blueprint's objectives, such as:

- Adopting a life-cycle approach in the regulation of therapeutic products, as opposed to the current point-in-time approach;
- Strengthening post-market surveillance and risk communication;
- Addressing product categorization issues and irritants - for example, some low risk products that are regulated under the *Natural Health Product Regulations*;
- The modernization of the food regulatory system;
- Continued progress in enhancing the transparency and openness of our activities, as well as our accountability to Canadians; and
- Better synchronizing of research and development and of regulatory and health system objectives.

Many participants noted that the fundamental role of Health Canada in protecting the health and safety of Canadians was not adequately reflected in the Blueprint and should be articulated clearly in future documents.

Some gaps in the Blueprint were identified by participants. Two gaps in particular were mentioned at all the regional discussion sessions:

- much more needs to be done in the area of compliance and enforcement, both at the levels of authorities and capacity; and

- there should be a greater focus on consumer information and the role that Health Canada, as a source of independent authoritative information, could play in this area.

Participants felt that successful implementation of the Blueprint would require adequate and sustainable resources, including a renewed cost recovery regime and new legislative tools. They also noted that the Blueprint is ambitious and will require setting priorities. The inclusion of an implementation plan with timelines for the various initiatives was recommended.

Blueprint for Renewal II—A Revised Framework

During the fall 2006 Blueprint regional consultation sessions, Health Canada promised to update the Blueprint document and framework to include the important feedback we received during the consultations.

Blueprint for Renewal II fulfills our promise and incorporates the following improvements:

- The Vision and Mission statements clearly articulate Health Canada's overarching goal of protecting the health and safety of Canadians.
- Specific objectives for compliance and enforcement and consumer information have been added.
- More detailed plans related to the implementation of the various Blueprint objectives and initiatives have been included.

Other stakeholder suggestions have been incorporated, as appropriate, throughout this document and under the various Blueprint initiatives.

Health Canada's *Blueprint for Renewal II*–A Revised Framework

Our Vision

To play a vital role in protecting and promoting the health and safety of all Canadians by excelling as a trusted scientific and regulatory authority for health products and food in Canada and internationally.

Our Mission

We help Canadians maintain and improve their health by:

- Evaluating and monitoring the safety, quality and efficacy of health products they use; the safety and quality of the foods they eat; and the safety, quality and effectiveness of veterinary drugs to protect the safety of Canada's food supply.
- Developing, promoting and implementing nutrition and food policies and standards.
- Providing timely, evidence-based and authoritative information to allow healthy and informed decisions.
- Anticipating and responding to public health and safety issues associated with health products, food and nutrition.

Blueprint Objectives

❶ Health Canada will develop a regulatory approach that recognizes health products have a "life cycle." Instead of discrete interventions at rigidly defined points (e.g., clinical trials or market authorization), a life-cycle approach will encompass all stages of product development and use.

❷ Health Canada will move toward a more transparent and consistent system of categorizing products and assessing their risks, thereby promoting regulatory interventions proportional to risk.

❸ Health Canada will put in place modern legislative, regulatory and policy tools to better support its compliance and enforcement functions and activities.

❹ Health Canada will design and implement a modern, efficient and responsive food regulatory framework that protects and promotes human health, responds to emerging food safety and nutrition challenges, and minimizes unnecessary delays in bringing safe food and food products to the Canadian marketplace.

❺ Health Canada will move the regulatory system away from a reactive "waiting for events" approach to a proactive approach that engages stakeholders and helps influence the future, today.

❻ Health Canada will use the regulatory system to better generate, disseminate and respond to safety and effectiveness data for health products and food. It will move towards a more proactive, post-market evaluation strategy.

❼ Health Canada will strengthen its leadership on a range of health and safety issues affecting specific populations that pertain to food, nutrition and health products.

Health Canada's *Blueprint for Renewal II*–A Revised Framework

Blueprint Objectives (continued)

❽ Health Canada will promote a more open and transparent regulatory system in which the involvement of patients, consumers, health professionals and researchers contributes to better overall quality of regulatory decision making.

❾ Health Canada will work with partners in the health care system to make available more and better information about health products and food to enable Canadians to make informed decisions about their health.

❿ Health Canada will work to better synchronize the regulatory system with the objectives, policies and practices of the health care and innovation systems.

Critical Success Factors

- A 21st century toolkit - legislation, regulatory frameworks and instruments;
- Internationally benchmarked regulatory practices, processes and risk management;
- A sustainable, high-performance, science-based organization;
- Strategic international regulatory cooperation; and
- Enhanced partnerships and stakeholder involvement.

Part 2—Objectives of the Blueprint and Planned Initiatives and Activities

Objective 1—Moving to a product life-cycle approach

Health Canada will develop a regulatory approach that recognizes health products have a "life cycle." Instead of discrete interventions at rigidly defined points (e.g., clinical trials or market authorization), a life-cycle approach will encompass all stages of product development and use.

For some time the prevailing role of the federal government in regulating drugs has been to guard Canadians from drug tragedies, such as the thalidomide events in the 1960s. The harms caused by thalidomide called for a system that could account for the fact that drugs can have risks even when they are beneficial, and that in some instances the risk outweighs the benefit of using the drug. The regulatory model for that time focussed on prohibiting the sale of drugs until they were carefully tested.

While traditional pre-market evaluation of drugs has worked well for many years, we know that it does not identify all the significant information about drug benefits and risks. While the medical and scientific staff in Health Canada have kept pace and adopted many international best practices for the review of drugs over the years, the regulatory support for these practices has not been modernized. As new developments overtake the old model, numerous limitations have been emerging in the regulatory structure, many of which raise fundamental questions as to the role of Health Canada in regulating drugs.

A health product’s benefits and risks should be evaluated throughout its life cycle, since additional knowledge is gained once a product is being used. Adopting a life-cycle approach for health products would allow for continuous evaluation of the safety, efficacy and quality of products before and after their introduction to the Canadian market.

A number of initiatives under the Blueprint will contribute to strengthening safety oversight at all stages of the life cycle of health products.

A progressive licensing framework for pharmaceuticals and biologics

Health Canada is developing a Progressive Licensing Framework for pharmaceuticals and biologic products.

The central concept of progressive licensing is that, over time, there is a progression in knowledge about a product and that this increase in knowledge can allow for the benefits of a drug to be maximized and its risks minimized.

The framework supports evidence-based decision making. Not only will the key regulatory decisions throughout the product life cycle be based on evidence, but so will the policy choices for the framework, including evaluating how the framework is achieving its objectives.

Good planning will be another key feature of the framework. Planning at every step of the regulatory process will be introduced to allow a proactive approach to managing expected and unexpected issues. From the very beginning of the regulatory cycle, Health Canada can make best use of its science and regulatory resources, for example, by agreeing with a manufacturer on when a regulatory filing will be made and what data it will include. Early planning and assessment of clinical trial methods and protocols could reduce the number of trials that yield inconclusive or irrelevant results from a regulatory point of view. Planning for post-market activities—including studies, effectiveness monitoring, safety surveillance and risk management—at the pre-market filing stage would ensure that expectations for identifying and managing drug benefits and risks are established before a drug is marketed. Similarly, planning for changes in manufacturing to take advantage of a pre-approved range of parameters would reduce unnecessary filings and ensure that a drug remains of high-manufacturing quality over its life cycle.

Accountability is incorporated into all aspects of the framework and reflects the ongoing requirement of Health Canada and drug manufacturers to justify the marketing of a product. The mechanisms for accountability in the framework include Health Canada's ability to set conditions when issuing an initial market license, so that, for example, certain field reporting commitments or further studies are required.

A concept paper for the framework was developed in fall 2006 and is available on the Blueprint for Renewal Web site (www.healthcanada.gc.ca/hpfb-blueprint). A series of discussion documents on specific themes will also be posted in early spring 2007.

HPFB hosted a two-day workshop on Progressive Licensing in November 2006 and invited 100 key stakeholders to participate. Participants came from all stakeholder groups, including patients and consumers, industry, academia, healthcare professionals, and provincial representatives.

The workshop encouraged participants to bring their own issues forward for discussion. As a result, they identified seven key priorities and made recommendations that will guide the next phase of the project, (results are posted on the Blueprint Web site).

A new regulatory framework will be built, based on the identified core concepts and ongoing development work with stakeholders through the spring and summer of 2007.

The public will have another opportunity to provide their comments on the design of the framework during a formal consultation period after publication in Canada Gazette I. We will analyze the comments and consider them when we revise the proposed regulations. Once the regulations are revised and published in Canada Gazette II, they will come into force.

Review of the Special Access Programme

Health Canada's Special Access Programme provides Canadians with limited access to drugs and medical devices that cannot otherwise be sold or distributed in Canada. Authorization for access is provided to health care practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, unavailable or offer limited options.

Unlike new drug submissions and clinical trials applications, health products released through the Programme are not subject to a detailed regulatory review. This supports the intent of the Programme to allow for decisions to be made quickly within the context of a medical emergency.

The regulatory framework to support the Programme was established in 1966 and a comprehensive review is required to modernize the framework and further define authorities. The review will explore specific issues, including:

- clarifying the circumstances under which authorization may be issued, subject to a more detailed review, or denied;
- provisions for authorizations to be further reviewed in circumstances where circumvention of clinical trial or new drug submissions requirements are suspected; and
- authorities for block releases of products in the event of a public health emergency.

A modernized framework would further define:

- the mandate and authorities of the Programme;
- encourage the appropriate use of the Programme; and
- establish an ethical framework for permitting compassionate access to new therapies outside of clinical research.

A draft guidance articulating the current mandate, intent and scope of the Programme was published in January 2007 and is available at www.hc-sc.gc.ca/dhp-mps/acces/drugs-drogues/sapg3_pasg3_e.html

The comprehensive review of the Programme will include:

- an operational review to evaluate how the Programme is functioning within its existing framework, and
- an ethics review to inform the development of options to modernize the Programme.

Stakeholders and Canadians will have the opportunity to contribute to the review. Consultations are targeted for fall 2007. The regulatory amendment to permit the block release of non-marketed drugs for health emergency or bio-defence situations is expected to be published in Canada Gazette I in June 2007.

Review of the regulatory framework for clinical trials

A new regulatory framework for clinical trials for drugs involving human subjects came into force on September 1, 2001 with two overarching objectives:

- to strengthen protection for human research participants; and
- to attract and sustain investment in research and development in Canada.

These changes affect both the regulator and stakeholders. Health Canada pledged to assess the impact of the regulatory changes and is working to ensure that the clinical trials regulatory framework is flexible, robust, and able to respond to pressures and trends.

A review of the regulatory framework for clinical trials was launched in 2006. An initial electronic consultation took place in the summer of 2006 to seek input from the public and stakeholders on the impact and effectiveness of the 2001 regulatory amendments and on ways to improve the framework. The report from this electronic consultation is available on the Blueprint for Renewal Web site at www.healthcanada.gc.ca/hpfb-blueprint.

The input from the electronic consultation indicated that the 2001 regulatory framework for clinical trials has generally delivered on its objectives. These objectives were felt to be still relevant for future needs but additional flexibility in the framework would be required to address emerging trends in the clinical trials environment—for example adaptative clinical trial design, emerging scientific fields such as pharmacogenomics, and the needs of specific populations. We also received important suggestions to improve the framework and its operation.

Building on the results from the electronic consultation, a consultation workshop was held in March 2007 to further explore options from the review. The discussion paper for this

workshop is available on the Blueprint Web site, and results from the workshop will be posted in spring 2007.

A new regulatory framework for blood and blood components intended for transfusion

The new regulatory framework addresses whole blood and blood components—for example red blood cells, platelets and plasma—intended for transfusion. The regulations will include requirements for collecting, importing, transforming and distributing allogeneic and autologous blood and blood components. All blood establishments, hospitals and health institutions that undertake these activities will be covered by the regulations.

The objectives of the new framework include:

- outlining clear and intelligible requirements;
- allowing for timely updating of the requirements as new technologies, products and issues emerge; and
- achieving greater harmonization within Canada for the collection, handling and post-approval surveillance of whole blood and blood components.

Health Canada established an Expert Working Group of independent experts to develop comprehensive standards for the safety of whole blood and blood components intended for transfusion. The Canadian Standards Association (CSA) was then contracted to publish and maintain these standards as national standards. Sections of these standards will be referenced in the new regulations.

The new regulatory framework for whole blood and blood components will build on existing blood safety programs in the provinces and territories, and on provincial-territorial efforts and successes in implementing the CSA standards for blood safety. This approach will bring HPFB closer to achieving the nationally harmonized blood regulatory framework recommended by the Krever Commission (Commission of Inquiry on the Blood System in Canada).

Consultations on the new regulatory framework are planned for spring 2007 and will include meetings with provincial and territorial stakeholders and a broad electronic consultation.

The proposed new regulations are targeted for publication in Canada Gazette I in fall 2007 and in Canada Gazette II in June 2008.

A new regulatory framework for human cells, tissues and organs for transplantation

Until now, certain human cells, tissues and organs (CTOs) for transplantation were regulated under three separate regulations:

- the *Medical Devices Regulations* (e.g., dura mater and heart valves);
- the *Food and Drugs Regulations* (e.g., blood); and
- the *Processing and Distribution of Semen for Assisted Conception Regulations* (e.g., semen for assisted conception).

For other tissues and organs, there were no specific regulations under the *Food and Drugs Act*. In addition, most establishments handling and processing CTOs lack specific safety standards, compliance monitoring and enforcement activities, and adverse event reporting that takes into consideration the unique characteristics of these products.

The new regulations will balance the need for safe, high quality CTOs for transplantation with the need to ensure their availability through the health care system. The new regulations are based on standards developed by the Canadian Standards Association, which were published in June 2003. The regulatory framework will be implemented in two phases:

- The first phase will put in place the basic safety requirements for CTOs as well as institute an establishment registration programme. Draft regulations were published in Canada Gazette I in December 2005. The new regulations will be published in Canada Gazette II in spring 2007.
- The second phase will enhance adverse event reporting requirements, as well as a compliance and enforcement strategy.

New regulatory frameworks for vaccines and radiopharmaceuticals

The existing regulatory framework for vaccines needs to be reviewed and updated to ensure that vaccine regulations are clear, timely and responsive to developments in biotechnology.

The current regulations governing vaccines are a mix of general regulations—applicable to all biologics, including vaccines—and vaccine-specific regulations. No new regulations have been introduced for vaccines discovered after 1963. However, since then, existing regulations have been updated or amended to respond to scientific advancements and changes in nomenclature. For instance, some sections were amended to be less prescriptive and allow flexibility in manufacturing protocols. Certain sections were repealed to remain consistent with legislative changes, such as the introduction of establishment licensing for biologics in 1997.

We will publish any regulatory amendments arising from the vaccines regulatory review in Canada Gazette I.

The regulatory framework for radiopharmaceuticals also needs to be reviewed and updated. The current regulations for radiopharmaceuticals are not flexible enough to accommodate the need to effectively regulate the safety, quality and efficacy of these products while still promoting access and addressing technological advances. In addition, there is a need for all applicable regulations to recognize the uniqueness of these products and their associated risks. Finally, there is little specific guidance and policies for stakeholders.

We are moving forward on two projects in this initiative:

- The first is regulatory amendments for basic clinical research involving radiopharmaceuticals (or positron-emitting radiopharmaceuticals). We have put in place an interim policy and expect to publish amendments to the relevant regulations in Canada Gazette I in spring 2007.
- The second is to require drug identification numbers on radiopharmaceuticals. The notification of regulatory amendments for this project is planned by the end of 2007.

Veterinary drugs: New measures on personal importation and labelling to protect Canadians

Health Canada is working to better address the health risks associated with using unauthorized veterinary drugs. All veterinary drugs must be reviewed by Health Canada before being authorized for sale in Canada. However, pre-market approval is generally not required for veterinary drugs imported into Canada when the drugs will not be sold or further distributed. As a result, unapproved drugs may be imported for “personal use”, even when the drugs are used in animals, including herds, owned by the importer which are intended for human consumption. Health Canada will develop an approach in 2007 to address this issue.

The Veterinary Drugs Directorate is also updating its 1992 guidance for the labelling of drugs for veterinary use. The goal is to develop a labelling guideline that would offer consistency to drug sponsors and to evaluators when preparing and reviewing drug labels, which includes the inner and outer label and package insert. This would provide the end user with clear and appropriate label information, resulting in more effective risk management. A draft guidance document will be ready for consultation in 2007.

Review of the medical devices program

In March 2004, the Auditor General of Canada released a report on Health Canada's Medical Devices Program. The report made recommendations on timely access, investigational testing, post-market activities, reuse of single-use medical devices and cost recovery. It highlighted that, with a rapidly changing technological environment and the increasing complexity and number of devices, the current program would require additional resources or need to be redesigned to address the increasing demands placed upon it. Health Canada accepted all of the recommendations and developed an action plan.

The Branch has initiated a number of measures as part of the plan:

- A director-general level steering committee, with a permanent secretariat, was established with members from the three directorates responsible for delivering the Program—the Therapeutic Products Directorate, the Marketed Health Products Directorate, and the Health Products and Food Branch Inspectorate. In addition to addressing the issues identified in the Auditor General's report, the committee provides oversight and direction for Program objectives, goals, targets, and expected results according to available resources and the Program's vision.
- Since 2004, the program has improved its pre-market review performance by eliminating its backlog and achieving 81 percent of decisions made within performance targets for all Class II, III, and IV applications in 2006. We have also implemented an active inspection program, developed an action plan to address risks posed by unlicensed medical devices, enhanced Branch surveillance capacity and continued to improve the way we communicate safety concerns to consumers and health care professionals. Further commitments over the next few years include implementing a Canadian Sentinel System to enhance post-market surveillance, and a market survey program to verify that medical devices for sale meet the licensing requirements.

Several significant international projects are also underway:

- Health Canada and the U.S. Food and Drug Administration are developing a partnership to allow a single, multi-purpose quality management system audit to be conducted by an auditor to cover the regulatory requirements of both jurisdictions.
- Health Canada and Australia's Therapeutic Goods Administration are developing a memorandum of understanding for the mutual recognition of their respective quality management systems certifications for medical device manufacturers.

- Health Canada continues to be an active participant of the Global Harmonization Task Force, which aims to harmonize regulatory standards for medical devices for use by all countries.

The reuse of single-use devices has been a major effort involving stakeholder consultations and a Scientific Advisory Panel. The Department is currently considering options for creating a policy position on the reuse of single-use devices.

We have developed a strategic plan for the program, which outlines future challenges and needs, as well as strategies to strengthen the program over the longer term. The plan defines five strategic objectives to improve our work environment and ensure that we manage our resources strategically. The strategic plan also discusses the program's need for adequate, consistent and reliable resourcing, which will be captured within the broader program and resource review exercise that has been undertaken by the Branch. The plan will be available on the Health Canada Web site in spring 2007 at www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/index_e.html.

Objective 2—Moving to regulatory interventions proportional to risk

Health Canada will move toward a more transparent and consistent system of categorizing products and assessing their risks, thereby promoting regulatory interventions proportional to risk.

The current patchwork of product categories and regulatory frameworks (e.g., drugs, natural health products, cosmetics, food) creates inefficiencies, including:

- lack of clarity and administrative delays in product reviews; and
- inconsistent approaches across regulatory frameworks for standards of evidence, health claims and risk-based regulatory responses.

The Health Products and Food Branch is currently reviewing a number of its product-specific regulatory frameworks—including those for pharmaceuticals, biologics and natural health products—to put in place consistent risk-based approaches in and across regulatory frameworks.

An improved product categorization system

Categorization of products is the process that allows regulators to decide which legislative and regulatory group or class, with its associated authorities and requirements, applies to a given product. This process is essential to ensure that a product submission is evaluated based on the measures and standards appropriate to the characteristics and risks of the product.

The number of products that challenge the current categories has increased. The regulatory system is now faced with products that do not fall easily under the traditional understanding of terms such as "food," "drug" or "cosmetic." New products—such as medicated shampoos, specialty teas that claim to have medicinal properties and cosmetic contact lenses—could be covered by more than one category in the current regulatory system.

Health Canada will renew the product categorization system so that regulatory requirements and interventions within and between regulatory frameworks are proportional to risk, and program investments are focussed on higher-risk products. A current example of this approach is the risk classification system for medical devices. A similar risk classification system could be applied to other regulatory frameworks where it makes sense, for example for natural health products.

A renewed system could also facilitate the approval of new uses for products that might otherwise be delayed because of an unnecessarily restrictive regulation that is not consistent with scientifically established or known low risks.

Health Canada is also committed to a more transparent approach to product classification decisions so that sponsors are aware of decisions and their basis. Recent progress has been made in this area with the establishment in January 2007 of a Committee on Product Classification, which will help resolve product classification issues in an efficient, timely and transparent way.

We will also consider policy and administrative solutions for more efficiently regulating products that overlap between various regulatory frameworks. Recent examples include the development of :

- a harmonized monograph system for low-risk products to streamline the assessment process for manufacturers; and
- a draft guidance document on the classification of cosmetic/drug borderline products; the guidance will be published for consultation in spring 2007.

We will make legislative and regulatory changes as required in the medium- to long-term.

Review of the *Natural Health Products Regulations*

The *Natural Health Products Regulations* came into force in January 2004 following extensive consultations. The development of the regulations was in response to the need for appropriate regulatory oversight of natural health products (NHPs) in Canada, which previously fell under the authority of the *Food and Drugs Regulations*. When the regulations came into force, a commitment was made to undertake a review of the regulations within the first three to five years of their implementation.

Several challenges have been identified as the regulatory requirements were put into practice. Lessons learned in implementing the regulations have led to a number of improvements in the Natural Health Products Directorate to enhance regulatory performance in issuing product and site licenses. For example, decisions on license applications are being made six times faster than in 2005, representing a 400% decrease in decision-making time. We expect to have addressed remaining processing delays in applications by the end of the 2007-08 fiscal year.

At the same time, we identified opportunities for refining the regulations through internal assessments and meetings with stakeholders (for example, issues related to natural health products that cross into other regulatory frameworks and product categories such as drugs, cosmetics or food).

In 2006, we launched a review to address these regulatory and operational issues. Working with internal and external stakeholders, we identified issues, options and solutions. Overall,

stakeholders support the NHP regulatory framework but feel that changes are needed to ensure that progress is effective and sustainable in the long term.

Health Canada will undertake further consultations as part of its review of the *Natural Health Products Regulations* in two phases:

- The first phase is a broad consultation to allow stakeholders to review and comment on issues we have identified. To support this phase, we launched an online consultation with a discussion paper in March 2007 on the Blueprint Web site (www.healthcanada.gc.ca/hpfb-blueprint). Input received will be used to develop preliminary options and an action plan.
- The second phase will include seeking input from targeted stakeholders on the options and action plan. We will consult more broadly on specific issues as required.

Health Canada is also considering the development of a new regulatory framework for veterinary natural health products. Consultations are planned for the summer of 2007.

Objective 3—Moving to strengthen compliance and enforcement

Health Canada will put in place modern legislative, regulatory and policy tools to better support its compliance and enforcement functions and activities.

In today's complex regulatory environment, HPFB must be equipped to act appropriately in a variety of situations to best mitigate risk and foster compliance. Having a good understanding of the sectors we regulate is imperative. Likewise, it is important to have a sufficient array of tools and measures to evaluate the impact of our work on compliance levels. The proposed compliance and enforcement strategy will allow for this and ensure effective and efficient compliance monitoring and enforcement.

The Branch plans several key steps under the strategy:

- environmental scans of regulated sectors, and communication with key sectors;
- expansion of the spectrum of compliance instruments, including new legislative and regulatory authorities and non-legislative tools;
- an assessment of how risk has evolved in the regulation of the health product sector; and
- development of performance indicators for measuring the effectiveness of compliance and enforcement activities.

Work is underway to complete the environmental scans of regulated sectors. We have started collecting basic information on key sectors, including the number of companies in operation, their location, and the activities they undertake. We will complete this work by April of 2007 and use it to solicit input from regulated sectors on HPFB's approach to compliance and enforcement.

The Branch will also work to strengthen its legislative and regulatory authorities for compliance and enforcement—for example, authorities to order corrective actions and modernization of the current fines and penalties framework. We are also developing complementary non-legislative tools to allow inspectors to use authorities in the most effective way possible—for example a ticketing regime and posting material on compliance and enforcement actions on the Health Canada Web site. Both initiatives will be launched in late 2007 or early 2008.

We are also looking at strategies to address issues related to counterfeit health products and to strengthen oversight of health products coming into Canada from other countries. These projects will also be completed by late 2007 or early 2008.

Objective 4—Moving to a modernized regulatory approach for food safety and nutrition

Health Canada will design and implement a modern, efficient and responsive food regulatory framework that protects and promotes human health, responds to emerging food safety and nutrition challenges, and minimizes unnecessary delays in bringing safe food and food products to the Canadian marketplace.

Food and food products constitute a special consideration for Health Canada. Access, both physical and economic, to safe and nutritious food is among the most basic, fundamental and unique determinants of population health. Few governmental tasks are as central to the everyday lives of Canadians as the responsibility to ensure that the food Canadians buy and eat is safe and nutritious, and that Canadians can rely on the truthfulness and accuracy of any claims or advertising made while making choices about food sold in Canada. It is also critically important that Health Canada's regulatory system for food and nutrition be able to respond to new challenges – irrespective of their origin – to the effectiveness of regulatory standards, and the ability of such standards to be active and positive contributors to improved health for all Canadians.

To this end, and recognizing the significant differences between regulatory concerns for foods versus health products, Health Canada is developing a Regulatory Modernization Strategy for Food and Nutrition (RMSFN) that will focus on bringing Health Canada's food

regulatory system more in line with the expectations that Canadian consumers and industry have for an efficient, effective, understandable, and accessible system that is flexible and responsive to the food safety and nutrition challenges of today and the future.

The main policy goals of the RMSFN, which are intended to set broad policy direction for key elements of Health Canada's food regulatory program, are as follows:

- **Improving predictability, effectiveness, efficiency, and transparency in health canada's food regulatory system**, including improving Health Canada's processes for pre-market regulatory clearances and notifications (e.g., for food additives);
- **Promoting regulatory responsiveness to food innovation and promoting consumer access to foods with assessed health benefits**, in particular, the development of a comprehensive approach for the management of food with health claims and completion of a policy on the discretionary fortification of foods;
- **Modernizing the regulatory toolkit to address "food contributors" to chronic disease** such as the development of strategies to reduce the presence of trans fatty acids in Canadian diets to the lowest possible levels;
- **Improving health canada's responsiveness to acute food safety health risks – responding to new threats while managing ongoing risks,** such as partnering with both government and non-government stakeholders in implementing a comprehensive strategy on food allergens and enhancing the effectiveness of risk communications for food safety and nutrition risks, consumer-level education, and retail-level food labelling for improved public health and consumer protection; and
- **Promoting a sustainable and integrated system for food safety and nutrition in Canada,** especially by strengthening and deepening collaboration between Health Canada, the Canadian Food Inspection Agency, the Public Health Agency of Canada, and the food safety authorities in the provinces and territories.

A discussion document articulating this new Strategy will be available on the Blueprint for Renewal Web site in the spring of 2007. A discussion document on a proposed approach for food-related health claims will also be published for consultation in the spring of 2007.

Objective 5—Moving to a proactive and enabling regulatory system

Health Canada will move the regulatory system away from a reactive, waiting-for-events approach to a proactive approach that engages stakeholders and helps influence the future, today.

In light of rapid advances in science and technology and to respond to the evolving needs of stakeholders and Canadians, the Health Products and Food Branch is putting in place a number of measures to strengthen its scientific and regulatory tools, processes and capacity. These measures will contribute to a more proactive, efficient and enabling regulatory system, as well as foster innovation and improved health outcomes for Canadians. More specific plans related to the initiatives noted below will be articulated in the HPFB Strategic Science Plan, which will be released by fall 2007.

Regulatory foresight and guidance

As technologies continue to evolve, converge, and be used in innovative applications, regulators must not only keep pace, but be ahead of the trend where possible. This requires the capacity to forecast and quickly adapt to new developments.

Health Canada will establish a regulatory foresight program and proactively develop or adapt regulatory guidances from other regulatory or harmonization bodies (e.g., International Conference on Harmonization) to outline regulatory requirements for new technologies and clinical research processes (e.g., for radiopharmaceuticals).

The Branch's Veterinary Drugs Directorate has drafted guidelines for new drug submissions to assist sponsors in developing quality submissions, which will result in a more efficient drug review process. The draft guidelines were posted on Health Canada's Web site for consultation in July 2006 and the Directorate held a workshop in November 2006 with the Canadian Animal Health Institute and its members, as well as other organizations to discuss the guidelines. The revised guidelines will be implemented and posted on the Web in 2007.

Scientific and regulatory advice to industry at early stages of product development

Providing scientific and regulatory advice at early stages of product development to industry— including small and medium enterprises—could help sponsors be better prepared to meet Health Canada's requirements for regulatory review. For example, discussions at early stages on the science of new treatments or on generating relevant information at early stages of the product life cycle could contribute to efficiencies in the development and review of a product, foster innovative technologies and therapies, and facilitate earlier access for Canadians to safer health products.

The Branch will provide scientific and regulatory advice on research and development relating to the quality, safety and efficacy of health products. This will help address challenges in the product development process by:

- providing better safety data on new and innovative drug products, thereby increasing the effectiveness for generating, collecting, disseminating, and using safety data;
- considering post-authorization, pharmacovigilance and risk management planning earlier to improve the quality of product submissions (including through the new progressive licensing framework); and
- generating greater health benefits from investments in research and development by increasing the number and quality of new products completing the drug development process that address unmet health needs.

Advice provided to sponsors through early engagement and structured pre-submission meetings would also help improve the quality of submissions, as well as the predictability of the regulatory process.

New and flexible regulatory frameworks and tools to reflect advances in product development

The Branch will continue to adapt its regulatory system to new science and technology. For example, we are currently developing new regulatory frameworks for radiopharmaceuticals and vaccines, as well as a regulatory pathway for subsequent-entry (generic) biologics.

We will collaborate with national and international research organizations in developing and validating biomarkers, which will contribute to a more efficient and effective product development process and increase their use in clinical practice and real-world safety and effectiveness evaluation.

Meeting internationally benchmarked performance targets for all regulated products

Through the Therapeutics Access Strategy, the efficiency and timeliness of the Branch's product review system has significantly improved since 2003. Backlogs in the review of pharmaceutical and biologic submissions were eliminated in September 2005 and September 2006 respectively. We are now meeting internationally benchmarked performance targets for the review of new drug submissions for pharmaceuticals, biologics and medical devices. As a consequence, median and average review times have been reduced substantially.

Investments in project management and scientific review capacity have contributed to these improvements in our pre-market review performance, without compromising Health Canada's high standards of safety.

Building on this success, we will establish and meet internationally benchmarked performance targets for all regulated products, including pre-market reviews of natural health products and veterinary drugs, and food products that require pre-market assessments.

Objective 6—Moving to a stronger post-market surveillance system

Health Canada will use the regulatory system to better generate, disseminate and respond to safety and effectiveness data for health products and food. It will move towards a more proactive, post-market evaluation strategy.

Health Canada has a key responsibility for surveillance of the safety and effectiveness of health products once they are on the market. Internationally, regulatory resources and tools have tended to focus on pre-market assessments and not on the monitoring of real-world safety and therapeutic effectiveness of health products.

Over the last decade, Health Canada has substantially strengthened its post-market surveillance capacity and infrastructure, including:

- establishing the Marketed Health Products Directorate (MHPD) in 2002;
- launching the MedEffect Web site in 2005;
- the opening in 2005 of two new regional monitoring centres in Alberta and Manitoba, bringing the total to seven centres;
- investing in MHPD's scientific capacity to assess safety signals; and
- improving the collection, analysis and dissemination of post-market safety and effectiveness information.

However, a number of challenges remain:

- Health Canada lacks regulatory authority to act effectively in the post-market area.
- Systems are in place to monitor spontaneously reported adverse events for health products and are being used to generate signals or hypotheses that can be prioritized and tested to determine causal associations between adverse events and product exposures. However, more proactive approaches could be implemented to improve collection, analysis and dissemination of health product safety and effectiveness information.

- We need stronger partnerships nationally and internationally to increase the available scientific expertise to generate and evaluate information on the safety and effectiveness of products on the market.

To address these challenges, we will be putting a number of measures in place, including:

- strengthening Health Canada's authority to obtain additional data on real-world safety and effectiveness of products (for example, requiring manufacturers to produce periodic safety update reports and post-market studies);
- expanding international regulatory cooperation, including upgrading the Canadian Adverse Drug Reaction Information System to access the U.S. Food and Drug Administration's and other regulatory agencies' adverse reaction data, which will facilitate in-depth safety data analysis and proactive risk management;
- implementing initiatives to address under reporting of adverse drug reactions;
- developing active surveillance systems that build on results of a recent paediatric pilot project between Health Canada, the Canadian Paediatric Society and the Children's and Women's Health Centre of British Columbia;
- through Budget 2005 investments, increasing Health Canada's scientific and research capacity to assess safety signals;
- improve the efficiency of risk communication to the public and health professionals on the Web and at point of care; and
- establishing an expert advisory committee on the vigilance of health products in 2007.

Under the National Pharmaceuticals Strategy, federal, provincial and territorial governments have recently developed a business case for a national research network of centres of excellence that, in principle, could be used to investigate priority signals of safety and effectiveness, as they are identified by monitoring systems.

In addition, Health Canada will seek opportunities to strengthen the Canadian health care system's capacity to report, analyse and manage medication incident data on a national basis, including through collaboration with the Canadian Patient Safety Institute.

Additional details on the Branch's efforts to strengthen its post-market surveillance system will be available in the Post-Market Surveillance Strategic Plan, which will be posted on the Blueprint for Renewal Web site in spring 2007.

Objective 7—Moving to an emphasis on specific populations

Health Canada will strengthen its leadership on a range of health and safety issues affecting specific populations that pertain to food, nutrition and health products.

A patient's response to drugs can vary significantly according to age, gender, and other factors. Health Canada, like other regulators, is challenged to ensure that health products take into consideration the special therapeutic needs and vulnerabilities of specific populations, such as children, the elderly, and pregnant or nursing mothers, among others.

For example, children are not "small adults" whose dosages and indications can be determined proportionally from body size. Instead, there can be metabolic and other physiologic differences that cause children to react to health products quite differently from adults.

Furthermore, with progress in science, in particular pharmacogenomics, more products will be tailor-made for diseases that affect smaller groups of patients or genetically specific populations.

The unique vulnerabilities of specific populations — children, seniors, Canadians with celiac disease, the immuno-compromised, Canadians with food allergies — are already part of food safety evaluations and risk assessments. Today's challenge is to facilitate innovation in the development of food products in such a way that food choices are increased for all individuals while the safety of the food supply is maintained.

The Office of Paediatric Initiatives

We have made progress on meeting the specific needs of children through the recent establishment at Health Canada of an Office of Paediatric Initiatives. The Office is seeking to engage stakeholders in exploring ways to strengthen paediatric therapeutic and nutritional information and is intended as a pilot and possible model for addressing the needs of other specific populations.

Improving the management of health product and food safety risks and benefits for children is a shared responsibility among health care providers, industry, governments and Canadians. The Office of Paediatric Initiatives draws from expertise across the Health Products and Food Branch and facilitates focus and cooperation on paediatric issues through a consultative approach with the various Branches of Health Canada, the Public Health Agency of Canada and external stakeholders.

Other recent examples of progress include the following:

- In the fall of 2006, a regulatory incentive for paediatric studies came into force in Canada through an amendment to the *Food and Drugs Regulations*. A six-month data protection extension, a form of market exclusivity, is now available to pharmaceutical companies who submit paediatric clinical trial information as part of an innovative drug submission.
- The Health Canada Web site now has information specific to the use of natural health products in children. An addendum to the Compliance Policy for Natural Health Products identifies products with a history of safe use in children, e.g., multi-vitamins and botanicals).
- Work is underway in the Office of Paediatric Initiatives to establish a Paediatric Expert Advisory Committee to provide advice on regulatory and related issues regarding health products and food used in children. The nomination call was conducted publicly over the Web. The Committee is expected to serve as a model for the Department to engage others on regulatory issues for specific populations in the future.

We have made provisions to have other specialized groups provide substantive, issue-specific or product-specific technical and scientific advice on children's issues. In addition, through the Progressive Licensing Framework, we will consider mechanisms that allow earlier access to health products to address unmet health or therapeutic needs of specific populations.

Objective 8—Moving to increased transparency and openness

Health Canada will promote a more open and transparent regulatory system in which the involvement of patients, consumers, health professionals and researchers contributes to better overall quality of regulatory decision making.

Canadians are seeking opportunities to participate and be more aware of decisions that may affect their health. Transparency and openness are fundamentally good regulatory practices that enhance the quality of decision making. The benefits include broadening the evidence and perspectives available to decision makers. An open approach makes regulators more efficient by improving relationships with stakeholders, promoting successful implementation of decisions, and building public confidence.

To promote increased openness, transparency and accountability, Health Canada will continue to use innovative methods and implement such measures as:

- a policy to guide consideration of public input in its decision making on regulated products;
- enhanced public access to information on clinical trials and their results; and
- improved access to information on the basis for regulatory decisions on newly approved products.

HPFB Review of Regulated Products: Policy on Public Input

Current legislation and policy frameworks in Canada provide little direction on how or when public input should be considered in regulatory reviews. The Health Products and Food Branch has historically involved external experts through the use of advisory bodies. In 2005, the Branch established a Public Involvement Framework, which articulates broad public involvement principles and commitments to guide the Branch in its public involvement activities.

That same year, the Branch held ground-breaking public forums, conducted as part of regulatory reviews of non-steroidal anti-inflammatories and silicone gel-filled breast implants. These forums identified a number of issues and gaps in the Branch's current ability to seek public input as part of its regulatory reviews. In the absence of legislative or regulatory clarity, a policy to guide and bring predictability to the Branch's public involvement efforts in key review areas has been developed.

The policy asserts that public input contributes meaningfully to regulatory decision making as a legitimate form of evidence that is relevant to the Branch's legislated mandate to evaluate the safety, effectiveness and quality of regulated products. It provides direction to reviewers and stakeholders on the specific circumstances in which the Branch may seek public input related to a product review. At the same time, the policy reflects the obligations inherent in HPFB's legislated relationship with industry as the regulated party, including protection of confidential business information and procedural fairness. In particular, the policy addresses the management of public input mechanisms, including advisory committees and public forums, as well as how public disclosure of review information, which is essential to support informed public input, will be managed by the regulator during a public input process.

Extensive consultations were held throughout 2006 on the policy. These included a public electronic consultation and stakeholder briefings and discussions with industry and patient representatives. Results indicated broad stakeholder support for the main elements of the

policy. They also demonstrated that there is widespread acceptance of the Branch's mandate to seek public input as part of regulatory decision making and that public input is relevant to the legislated criteria that HPFB must consider in regulatory reviews. The policy and the report from the electronic consultation are available on the Blueprint for Renewal Web site at www.healthcanada.gc.ca/hpfb-blueprint.

HPFB launched the new policy in March 2007 and will continue to work with stakeholders to further refine guidance materials that support the implementation of the policy. Work on the policy will also inform other Branch initiatives such as the Progressive Licensing Framework and the development of a consumer information strategy.

Registration and disclosure of clinical trial information

The registration and disclosure of clinical trial information has been identified as a key means of enhancing the transparency of clinical trials. Numerous domestic and international initiatives are currently underway to encourage or require registration in order to facilitate access to information about clinical trials.

In June 2005, Health Canada launched a series of consultations to identify the needs of users for the registration and disclosure of clinical trial information. Following these consultations, which consisted of three one-day workshops and an electronic questionnaire, Health Canada established an External Working Group to develop and advise on options for the registration and disclosure of clinical trial information.

The External Working Group, whose membership represents a range of stakeholder perspectives, held its first meeting in April 2006. The working group developed preliminary options, which were used for a second electronic consultation that took place from June to July 2006. The working group considered the results of this consultation in developing its final recommendations, which were provided to Health Canada in January 2007. Reports from these consultations and the External Working Group are available on the Blueprint Web site.

Results from the consultations revealed a strong consensus among stakeholders that a Canadian approach to registration must reflect stakeholder needs and be informed by international efforts in order to create a harmonised approach. This will allow for improved public access to relevant, accurate and meaningful clinical trial information while respecting the need for academic and commercial confidentiality as well as privacy.

Health Canada will start implementing an approach for registration in Canada in the summer of 2007 that reflects the input received from its consultations as well as work that is underway internationally.

Objective 9—Moving to more and better information about health products and food

Health Canada will work with partners in the health care system to make available more and better information about health products and food to enable Canadians to make informed decisions about their health.

Consumers want and expect authoritative, timely, and clear information to support informed decisions about their health in an environment where information on the risks and benefits of health products and food is increasingly complex and diverse.

This message was strongly articulated at the fall 2006 Blueprint regional consultation sessions by participants, who felt that the Branch should make consumer information and education a priority in an updated regulatory system. There were calls for better information to:

- physicians and other health care professionals, who need more information on the risks and benefits of products to support optimal prescribing and use;
- patients, who are increasingly calling for greater autonomy to make informed decisions about their health; and
- consumers and the public, who need to be able to understand how the regulatory system works, as well as the risks and benefits of the health products and food they are consuming.

Over the last few years, HPFB has undertaken several initiatives to address gaps in consumer information and education. This includes: developing education modules to allow patients and consumers to better understand the work of the Branch; launching the MedEffect Web site, which provides access to the latest advisories, warnings and recalls on health products currently on the market; and designing the Interactive Nutrition Label and Quiz Web site to help Canadians use nutrition information on food labels. The Branch now publishes a Summary Basis of Decision for all new active substances—biological and pharmaceutical—and certain high-risk medical devices that received market authorization after January 1, 2005. The Summary Basis of Decision outlines the scientific and benefit-risk based decisions that factor into Health Canada's decision to license a drug or medical device.

Development of a broader consumer information strategy and an outreach strategy is now underway. The consumer information strategy will:

- identify new and effective ways to improve the way HPFB communicates information to consumers;

- review the tools, practices, and partnerships through which the Branch currently communicates information and how these could be improved or expanded;
- examine how to get information to consumers when they need it and in a way that it can be more easily and effectively integrated into the choices that they make; and
- document some of the best practices from international regulators and other health organizations.

The outreach strategy will:

- expand the Branch's outreach capabilities to include under-served or emerging stakeholder groups;
- promote increased stakeholder and public understanding in key areas of the Branch's work, such as efforts to modernize the regulatory system and the important role of science in health product regulation; and
- support and enhance stakeholder relationships.

Building on feedback received during the Blueprint regional sessions, the Branch will complete a needs assessment for the consumer information strategy and recommendations by early spring 2007. These recommendations will be discussed with stakeholders.

Objective 10—Moving to an integrated system

Health Canada will work to better synchronize the regulatory system with the objectives, policies and practices of the health care and innovation systems.

Health Canada works collaboratively with partners and stakeholders in Canada and internationally. Many individuals and organizations share responsibility for the health and safety of Canadians. They include the provinces and territories, health researchers, health care providers, industry and individual Canadians. To better fulfill its regulatory responsibilities, Health Canada needs to develop clear roles and responsibilities with other players. This will ensure the independence of the regulatory system while allowing more focussed cooperation to achieve better health and food safety outcomes for Canadians.

Provincial and territorial governments have a direct interest in regulatory decisions taken by Health Canada on food, drugs, medical devices and other therapeutic products. For example, the National Pharmaceuticals Strategy directly and indirectly involves the regulatory system

in areas such as strengthening evaluation of the real-world safety and effectiveness of drugs, and accelerating access to breakthrough drugs for unmet health needs.

To move to a more integrated system, Health Canada will develop stronger partnerships with a number of organizations, for example:

- working with partners in the health care system (e.g., health care professionals, researchers, provinces and territories) to implement the Branch's Post-Market Surveillance Strategic Plan;
- improving communication and cooperation with the Canadian Agency for Drugs and Technologies in Health on the Common Drug Review;
- expanding partnerships with the Canadian Institutes of Health Research and other national and international research organizations on issues such as research on unmet health and therapeutic needs, biomarkers, specific populations, generation and assessment of real-world safety and effectiveness evidence; and
- continuing to seek out opportunities to align the regulatory system with international best practices, and where it is in Canada's interest, harmonize with other nations or international organizations, such as the World Health Organization, the International Conference on Harmonization, and Codex Alimentarius.

Health Canada will continue to work with key partners to advance objectives in the food and nutrition area. While the *Food and Drugs Act* governs the safety and nutritional quality of all food sold in Canada, significant activities exist outside of this legislative framework. Relationships between federal, provincial and territorial governments and food producer associations are also important to ensure the safety and nutritional quality of food.

Part 3—Implementation of the Blueprint

Starting in 2007, the Health Products and Food Branch (HPFB) will begin implementing key building blocks of our Blueprint for Renewal.

Critical Success Factors

We have identified five critical success factors that will support the implementation of the Blueprint and its objectives:

- a 21st century toolkit—legislation, regulatory frameworks and instruments;
- internationally benchmarked regulatory practices, processes and risk management;
- a sustainable, high-performance, science-based organization;
- strategic international regulatory cooperation; and
- enhanced partnerships and stakeholder involvement.

A 21st century toolkit—legislation, regulatory frameworks and instruments

We have a broad array of tools available to us to further public policy objectives, which could be applied across the product life cycle. They need to be selectively applied, depending on their appropriateness for achieving the vision and objectives in the Blueprint. Examples of instruments that may be used alone or in combination are:

- laws (statutes and regulations);
- performance-based regulations;
- enabling administrative protocols;
- policies, guidelines, standards, codes, registries and other voluntary actions; and
- information, education, research and collaborative partnerships.

Based on Health Canada's commitment to achieving the greatest benefit for Canadians, we will assess these tools according to their effectiveness, legality, compliance, fairness and socioeconomic impacts prior to selecting the appropriate ones for the circumstances.

Through Health Canada's legislative renewal initiative, HPFB will be looking to accelerate legislative changes in key areas, including seeking new authorities for compliance and enforcement and transparency and openness.

Internationally benchmarked regulatory practices, processes and risk management

Health Canada's Blueprint for Renewal will be rooted in a transformation of current business practices to increase efficiency, effectiveness, transparency and responsiveness. We will meet performance targets for all regulated products by increasing regulatory science and foresight capacity, use of science and technology, and international regulatory cooperation. Performance targets and standards will be established for those product areas not currently covered.

We will strengthen our science and risk management capacity by identifying key knowledge areas and anticipating trends in their development. Our science and risk management capacity is defined by the business processes that support how we gather evidence, generate new knowledge and make rigorous decisions. The goal is to use the best available, high-quality evidence in support of decisions that help to protect the health and safety of Canadians.

A sustainable, high-performance, science-based organization

The Branch has undertaken in 2006 a broad review of its programs and resources in order to define the level of activities, performance and resources required to meet its regulatory and other responsibilities. In 2007, we will develop a business case to articulate new requirements to sustain and improve future regulatory activities. This includes continued investments in scientific capacity, laboratory infrastructure, information management and information technology, etc., as well as requirements related to the implementation of the Blueprint for Renewal.

The Branch introduced user fees in 1994-95, which represent about 20 percent of overall Branch funding and 25 percent of the total cost of delivering the regulatory program for therapeutic products, including human and veterinary drugs and medical devices (currently, activities in the natural health products area are not covered). The Branch is authorized to collect up to $40.7 million in fees annually. The current fee structure is out of date with the scope and costs of regulatory activities.

Several countries have renewed their fee structures to address the costs of the regulatory system. One major driver for rising fees is the growth in post-market activities in response to increased public pressure and attention on drug safety. Public discussions are currently taking place in Australia, New Zealand and the United States on fee renewal for the regulation of therapeutic products, and the United Kingdom and the European Union are finalizing plans to introduce new fees.

On March 31, 2004, the *User Fees Act* became law in Canada. The Act links performance with new fees and requires fees to be internationally comparable and subject to parliamentary

oversight. In 2005-06, the Branch developed a cost recovery framework to provide coherence across its product and business lines. The framework looks at costing methodology, criteria for excluding or including activities for fees, the impact on service standards and their link to fees, annual reporting, and dispute management.

The Branch will finalize the cost recovery framework in 2007 and will consult stakeholders on fee proposals for individual product lines. Consultations on fees for all therapeutic products are planned for early spring 2007 and additional consultations will follow in 2007-08 for the regulatory review process. We anticipate that a new cost recovery framework will come into force in 2008-09, bringing stability and sustainability to our efforts to protect the health and safety of Canadians.

Strategic international regulatory cooperation

Over the past few years, HPFB has strengthened its relationship with key international counterparts and continued its efforts to harmonize technical requirements and standards. The Branch has worked with other international regulators to leverage resources; share information, knowledge and expertise; and adopt best practices. We have made substantial progress and have laid the foundation for developing smarter approaches to using our resources and scientific regulatory capacity.

We developed agreements with the U.S. Food and Drug Administration and Australia to further bi-lateral collaboration, such as confidentiality agreements. In 2006, we concluded a series of similar arrangements with China, Singapore and Switzerland. We also advanced collaborative work with the U.S. and Mexico under the Security and Prosperity Partnership of North America and the Tri-Lateral Accord.

Moving forward, Health Canada will continue to enhance international cooperation by focusing resources on optimizing work within existing agreements to improve regulatory performance and advance key policy objectives. This includes:

- targeting work-sharing activities that support domestic decision-making (e.g., real time information sharing on risk assessments and product reviews);
- maintaining international communication networks to allow early detection of safety issues such as product recalls and adverse events outside Canada;
- targeting strategic cooperation by product line or function, such as with Pacific-rim countries on traditional Chinese products and medical devices, and with Europe on pharmacovigilance;
- improving access to tools, training and best practices developed by leading regulatory counterparts; and

- negotiating new agreements of strategic importance to Health Canada's mandate, including with the European Commission and the European Medicines Agency, targeted for completion in 2007.

The Branch will also continue its efforts to harmonize technical requirements and standards for health products and food. It will seek opportunities to align the Canadian regulatory system with international best practices, and adopt or harmonize with those of other nations and international organizations as appropriate to the Canadian context.

Health Canada will continue strategic participation in negotiations of guidance and standards to influence global discussions and ensure that they take into account the Canadian environment for health products and food. This will involve continued Canadian participation in the activities of the International Conference on Harmonization, the Global Harmonization Task Force for medical devices, Codex Alimentarius and the Veterinary International Conference on Harmonization.

Health Canada will report on its progress on implementation of internationally-recognized guidance and standards. Pilot initiatives to seek input from Canadian stakeholders prior to international standards negotiations will also be undertaken.

Enhanced partnerships and stakeholder involvement

Health Canada is committed to involving the public and key stakeholders in implementing the Blueprint for Renewal. We plan to consult the public in 2007 on the Progressive Licensing Framework, the Cost Recovery Initiative, the Special Access Programme, the Regulatory Modernization Strategy for Food and Nutrition, and the review of the *Natural Health Products Regulations*. Additional opportunities, including bilateral meetings, workshops, and Web-based consultations, will be used to seek feedback in the fall and into 2008 as other initiatives are further developed. Regulatory changes will continue to be submitted to the Canada Gazette process.

Moving Forward and Reporting on Progress

The initiatives outlined in Blueprint II will be key to advancing the Branch's strategies outlined in the 2007-12 HPFB Strategic Plan. The Strategic Plan articulates the broader change agenda for the Branch for the next five years, and is available on our Web site.

Health Canada will continue to report on progress on the implementation of the Blueprint through the Blueprint for Renewal Web site (www.healthcanada.gc.ca/hpfb-blueprint), as well as through the Branch's annual performance reports. The Web site will allow stakeholders and the public to stay informed of new Blueprint developments and opportunities for involvement. Regular communications with stakeholders will also take place through HPFB's *Involving You* newsletter, as well as targeted mailouts and e-mails.