

# *Serving Canadians - Now and Into the Future*

Strategic Plan 2004-07 for Health Canada's  
Health Products and Food Branch



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Health Products and Food Branch

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Our Mission is to help the people of Canada  
maintain and improve their health.

*Health Canada*

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# Foreword

It is my pleasure to present to you the Health Products and Food Branch (HPFB) Strategic Plan for 2004-07.

Canadians place a high priority on the effectiveness and accessibility of our health system, and HPFB is a key player in ensuring that the system is working well. The broad scope of our mandate – which includes evaluating and monitoring the safety, quality and effectiveness of the drugs, vaccines, medical devices and other therapeutic products available to Canadians as well as the safety and quality of the foods we eat – means that the work we do touches the lives of every Canadian. Recognizing that the health of Canadians is a shared responsibility, we also strive to be a trusted source of authoritative health information, and work to promote conditions that enable Canadians to make healthy choices and informed decisions related to health products, food and nutrition.



This document represents a major milestone in HPFB's evolution as an organization committed to providing world-class delivery of its mandate and to meeting the needs of its diverse publics. Globalization, public health trends, as well as technological and scientific advances are converging to fundamentally change the regulatory environment and the role we play in it. Equally important, Canadians expect a greater degree of transparency, openness and accountability in the way we do our business. The Branch's Strategic Plan is our road map for anticipating, understanding and responding to these changes.

As you will note, the Plan identifies five key strategies, linked to overall departmental and government-wide commitments, that will guide our organizational activities over the next three years. It will serve as a constant yardstick against which we will make informed choices about our priorities and resources, put in place performance measures, and track and report on progress and accountabilities. Ultimately, the Strategic Plan serves as our tool for demonstrating progress against our commitment to serving Canadians more effectively and efficiently now and into the future. And it allows both the Branch and its stakeholders to share a common understanding of where we want to go and how we can work together to get there.

Through our Strategic Plan, HPFB is articulating a comprehensive and ambitious agenda, one that Canadians expect us to pursue with their best interests as our first priority. I know that, as we move forward, I can count on the ongoing support and dedication of our staff and the continued engagement and collaboration of our partners and stakeholders.

A handwritten signature in black ink, appearing to read 'Diane Gorman'. The signature is fluid and cursive, written over a white background.

Diane Gorman  
Assistant Deputy Minister

# Surveying the Landscape

Health Canada's Health Products and Food Branch (HPFB) is responsible for a broad range of health protection and promotion activities that affect the daily lives of Canadians. The Branch employs an integrated, science-based approach to managing the risks and benefits relating to health products, food and nutrition. Now more than ever, HPFB is working to anticipate and respond to the profound changes affecting food and health products in Canada, so that Canadians can continue to rely on us to help them maintain and improve their health.

## Globalization

Globalization in all its forms has made the role of governments in protecting the health and safety of their citizens increasingly complex. More open markets are facilitating not only the trans-border movement of capital and people, but also the rapid spread of diseases and pollution. Globalization has also blurred the distinction between the international and domestic arenas. Today, Canada's economic space is larger, and policy and regulatory issues are increasingly interconnected across borders and more complex.

The importance of dealing with these issues through integrated public policy and cooperation among all orders of government has similarly grown. The ability to regulate effectively at the national level now requires cooperation with the international community, but there is no simple formula for such cooperation. Some situations may benefit from informal approaches such as information sharing and international exchanges, while others demand more formal mechanisms such as treaty-based mutual recognition agreements.

## Science and Technology

Scientific and technological advances hold great promise for improving health, both directly, through more effective cures and preventive measures, and indirectly, through improvements in health systems and physical environments. The pace of scientific discovery in everything from informatics to nanotechnology and genomics is either already transforming or expected to transform everything from health products and food to communication about them.

Moreover, the boundaries between traditionally distinct science-based sectors have become blurred as the agribusiness, chemicals, health care and pharmaceuticals industries fuse and regroup in new forms. Biotechnology is delivering new diagnostic tools, novel drug therapies, new methods of disease prevention and novel food products.

Health Canada has identified six major trends that are shaping our technological and health future by transforming everything from the health products and food we consume to the way we communicate:

- informatics;
- nanoscale science and engineering;
- biotechnologies and beioenvironmental approaches;
- medical sciences and enhancement of the human body (including genomics);
- advances in the cognitive sciences; and
- collective behaviour and systems approaches.

The proliferation of new technologies requires new regulatory regimes that can stimulate innovation and public access to new therapies while safeguarding public health. In the face of such rapid change, regulators must remain astute predictors of new developments in the field and adept at evaluating the risks and benefits of more complex products and treatments.

## **Public Health**

Globalization has significant public health implications for regulators. More than two dozen new infectious agents have been identified in the last 30 years, almost one per year. More than 36 million people are living with HIV/AIDS worldwide, 50 percent more than was predicted a decade ago. Meanwhile, drug-resistant pneumonia, tuberculosis and malaria are also on the rise. Events like the international severe acute respiratory syndrome (SARS) outbreak, the emergence of West Nile virus in Canada and the discovery of bovine spongiform encephalopathy (BSE) in Alberta have kept public health issues in the spotlight and have underscored the challenges of an increasingly “borderless” world.

Canada’s approach to public health is also influenced by a growing incidence of non-communicable, chronic diseases, including cancer, diabetes, obesity and cardiovascular disease, both in Canada and abroad. The World Health Organization predicts that these diseases will account for 57 percent of human illness by 2020. Such illnesses lead to dramatic increases in health care costs, disability, work days lost and premature deaths. They have also brought about a more sophisticated understanding of public health within a global, social, economic and environmental context, including the need to improve public awareness of health issues and to strengthen local, national, and global health surveillance systems.

## **Transparency, Openness and Accountability**

Canadians expect their governments to be responsive, open and accountable. A more engaged and empowered public, coupled with the popularity of the Internet, is contributing to demands for more consumer information, more choice in health products and food, and a say in regulatory processes. At the same time, Canadians rely on the government to provide basic protections such as access to safe and affordable drugs and a safe and nutritious food supply.

Stakeholders want effective mechanisms to ensure that they are appropriately informed, that their views are heard, and that governments are held accountable for how their expertise and advice are used. This is particularly true in a regulatory context, where the actions and decisions taken by governments have real effect on the lives of Canadians and their ability to manage their health. It requires that regulators recognize the fundamental importance of public involvement and engagement, and that they build their own knowledge and capacity to support it.



# Government Commitments

Since the First Ministers Accord on health system renewal in September 2000, all governments have taken steps to improve the quality, accessibility and sustainability of Canada's public health system. In February 2003, First Ministers agreed on a new health plan to improve access to quality care for all Canadians. Among other commitments, the new *Accord on Health Care Renewal* commits the federal government and its provincial and territorial counterparts to work together to ensure that drugs are safe, effective and accessible in a timely and cost-effective fashion. This includes collaborating to promote optimal drug use, best practices in drug prescription and better management of drug costs.

In the *2004 Speech from the Throne*, the Government of Canada emphasized the importance of food safety, health promotion and a responsive public health system, and reiterated its commitment to working with its provincial and territorial partners in sustaining a universal, high-quality, publicly funded health care system.

The Government of Canada is also moving forward with a “smart regulation” strategy to accelerate reforms to the regulatory system in Canada that promote health and health system sustainability, contribute to innovation and economic growth, and minimize the administrative burden on business. A key part of the government's smart regulation strategy is the commitment to speed up the regulatory process for drug approvals to ensure that Canadians have faster access to the safe drugs they need.

## Therapeutics Access Strategy

Health Canada launched the Therapeutics Access Strategy in 2003. The strategy brings together the most creative thinking inside and outside government to transform Health Canada's approach to the regulation of health products and improve Canadians' access to those products. The objective of the Strategy is to ensure that human drugs and other therapeutic products are safe, of high quality, therapeutically effective, appropriately used and accessible in a timely and cost-effective fashion.

The Therapeutics Access Strategy will:

- improve the timeliness and transparency of the review process for therapeutic products while maintaining Health Canada's high standards for safety;
- improve Health Canada's ability to monitor the safety and therapeutic effectiveness of products once they reach the market; and
- contribute to the sustainability of the health care system by improving access to appropriate and cost-effective drug therapies for Canadians.



In Budget 2003, the Government of Canada allocated \$190 million over five years to the strategy, which includes measures to ensure that Health Canada has the right financial and human resource management tools to get the job done.

The HPFB Strategic Plan encompasses the objectives of the Therapeutics Access Strategy.

# Health Products and Food Branch (HPFB)

Canadians see good health as an important influence on our quality of life. The Health Products and Food Branch, as part of Health Canada, works to improve the lives of Canadians and to make this country's population among the healthiest in the world.

As Canada's federal authority responsible for the regulation of health products and food, HPFB evaluates and monitors the safety, quality and effectiveness of the thousands of drugs, vaccines, medical devices, natural health products and other therapeutic products available to Canadians, as well as the safety and quality of the foods they eat. The Branch's mandate includes ensuring that veterinary drugs sold in Canada are safe and effective for animals and that the foods derived from animals treated with those drugs are safe. HPFB also promotes the health and well being of Canadians through a broad range of activities relating to health products and food, including developing nutrition policies and standards such as *Canada's Food Guide to Healthy Eating*.

Sound science and effective risk management are at the core of what the Branch does and how we do it. These tools are integrated into the Branch's daily operations, and throughout the full spectrum of our responsibilities, which range from policy development, evaluation of health products and food, and nutrition surveillance to research into pharmacogenomics<sup>1</sup> and food pathogens.

HPFB delivers its responsibilities for health products, food and nutrition in all regions of Canada through offices across the country.

Many individuals and organizations share responsibility for the health of Canadians. They include the provinces and territories, health care providers, industry and Canadians themselves, whose individual choices and circumstances must be respected. To fulfill its responsibilities, the Health Products and Food Branch has developed strong partnerships with other branches of Health Canada, other federal government departments and other orders of government, as well as with academia and non-governmental organizations from across the country. The Branch also works bilaterally with health authorities in other countries and through international organizations and multilateral fora, to share information, increase regulatory cooperation and harmonize regulatory standards and processes.

## HPFB Mandate

The Health Products and Food Branch takes an integrated approach to the management of the risks and benefits to health related to health products and food by:

- minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and
- promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.

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<sup>1</sup> Pharmacogenomics: The study of how variations in the human genome affect the response to medications.

# Guiding Principles and Values

The following principles and values guide the day-to-day operation of the Health Products and Food Branch, describe how we aim to carry out our business, and articulate the results we strive to achieve:

- **Effectiveness** — The effectiveness of the Branch can be measured by the extent to which Canadians have access to safe, high-quality and effective health products, safe and nutritious food, and authoritative information for making informed decisions and healthy choices. To this end, the Branch collaborates with its partners and stakeholders to assess, communicate and manage the risks associated with health products, food and nutrition.
- **Efficiency** — The Branch delivers its programs in a timely, efficient and cost-effective manner, and uses public resources responsibly to optimize the value and benefits for Canadians.
- **Transparency** — The Branch ensures accessibility and transparency in its decision making and information sharing, in order to maintain and strengthen public confidence and trust in the regulatory system, the safety of health products and food, and ultimately Canada's health system.
- **Accountability** — The Branch ensures that its work serves the interests of Canadians and that the Branch is accountable for its results through government and public scrutiny.
- **Cooperation** — The Branch develops its policies and programs, informed by the views of the public and stakeholders, and with their involvement. It cooperates and collaborates with other jurisdictions, both within Canada and internationally.

## Health Canada's Values

The Branch undertakes its work on a foundation of public service values, including:

**Caring for the People of Canada:** The Branch advances the public good with purpose and passion while honouring democratic values, including:

- providing credible information, reliable advice and quality services;
- establishing and maintaining good working relationships with its stakeholders; and
- managing responsibly and wisely the resources entrusted to it.

**Taking Pride in What We Do:** Branch staff are motivated and guided by their personal integrity, including:

- realizing their potential;
- improving themselves and the way of doing things; and
- exercising sound judgement.

**Building a Workplace Community:** The staff respect each other and work together in a healthy environment, including:

- embracing diversity and nurturing empowering relationships;
- communicating honestly and effectively; and
- creating an environment that promotes learning and innovation.

# Meeting the Needs of Canadians — HPFB's Strategy for the Future

To help Canadians maintain and improve their health, the Health Products and Food Branch strives to ensure that they have timely access to safe and effective health products, safe and nutritious food, and the information they need to make healthy choices. To achieve this goal, the Branch will focus its efforts on five key strategies over the next three years:

- Transforming our efficiency, effectiveness and responsiveness as a regulator.
- Providing authoritative information to support healthy choices and informed decisions by Canadians.
- Increasing our responsiveness to public health issues and our vigilance over safety and therapeutic effectiveness.
- Improving our transparency, openness and accountability, to strengthen public trust and stakeholder relationships.
- Building a nationally-based, flexible organization that has the capacity to fulfill its mandate and priorities in a changing environment.

By aligning its work with these key strategies, HPFB will deliver results for Canadians, including:

- improved public health (e.g. the prevention and cure of chronic or life-threatening diseases) through timely access to needed health therapies and technologies that are regulated under the *Food and Drugs Act*;
- a world-leading food safety system that enjoys consumer confidence in Canada and abroad;
- improved healthy eating habits among Canadians, one of the key contributing factors to healthy human development, and lower risk of nutrition-related chronic disease;
- international recognition of Canada as a world leader in health product safety and effectiveness through fewer adverse reaction, and patient-safety incidents and improved prescribing practices and drug use;
- a regulatory system that provides a competitive advantage for Canadian innovations in areas such as biotechnology and health technologies;
- evidence-based risk management decisions and an ample supply of consumer information from trusted sources to support healthy choices; and
- improved public trust and confidence in Canada's regulatory system for health products and food.

# Strategy 1: Transforming Branch Efficiency, Effectiveness and Responsiveness as a Regulator

Health Canada's regulatory system and scientific capacity must keep pace with change, so that Canadians can continue to have confidence in its high standards of safety, and Canadian industry can benefit from an internationally comparable regulatory environment.

As science and technology evolve rapidly, with ever-shortening innovation cycles, the challenge for the Health Products and Food Branch is to ensure that new knowledge and technologies translate into tangible and improved health outcomes for Canadians and that the health products and foods available in Canada continue to deserve the confidence of consumers.

Canada's participation in an increasingly complex global system requires that all levels of government collaborate more effectively. Many opportunities for Canada to both contribute to and benefit from international regulatory cooperation and harmonization activities are emerging. HPFB is working to ensure that our international activities support timely public access to important new therapies and health technologies and allow quicker identification of risks associated with health products and food on the market, while safeguarding Health Canada's high standards for safety, efficacy and quality.

*Through this strategy, the Branch will deliver the following key results for Canadians:*

## 1.1 Transformed regulatory processes

Through the Therapeutics Access Strategy, the Branch will improve the timeliness, transparency and predictability of its regulatory processes for pre-market reviews of health products and food, benchmarking them against leading international practices, while maintaining Health Canada's high safety standards. The Branch will accomplish this by modernizing its regulatory review processes, increasing its science capacity, and applying project management and other quality systems to review processes. The Branch will apply these systems to submissions for the review of human and veterinary drugs, biologics and genetic therapies, medical devices, natural health products, and novel foods.

### *Strategy 1 Highlights*

- The Branch will meet performance targets on review of new drug submissions 90 per cent of the time in 2005–06 for pharmaceuticals and in 2006–07 for biologics and genetic therapies, including elimination of the backlog of submissions.
- The Branch will implement Good Guidance Practices to help industry improve the quality of submissions, as well as Good Review Practices to ensure high-quality reviews.
- The Branch will implement the Natural Health Products Regulations, which were introduced in January 2004.
- The Branch will develop an international regulatory cooperation strategy.
- The Branch will develop a national food safety strategy with the Canadian Food Inspection Agency, Agriculture and Agri-Food Canada, and provincial and territorial partners.
- Health Canada will develop a federal biotechnology stewardship framework.

## **1.2 A regulatory platform for the 21<sup>st</sup> Century**

The Branch will develop and apply innovative approaches to the regulation of health products and food, including flexible, risk-based regulatory frameworks. This supports the federal government's ongoing commitment to smart regulation and is linked to Health Canada's efforts to renew health protection legislation.

## **1.3 Expanded collaboration with international regulatory authorities**

Through expanded collaboration with its international partners, the Branch will leverage expertise and knowledge and ensure the application of sound regulatory practices and standards that are consistent, whenever possible, with leading international standards and norms. The Branch will also increase information-sharing and joint activities with international regulators to support more efficient and effective regulatory decision-making and enable quicker identification of risks associated with health products and food available in the market.

## **1.4 Leveraged national partnerships**

Recognizing that improving the health of Canadians is a shared responsibility, the Branch will seek opportunities to work closely with other levels of government and stakeholders to bring about improved health outcomes through cooperation and collaboration.

## **1.5 Enhanced health innovation**

Better health outcomes for Canadians require a regulatory environment for health and food products that is innovation-friendly. The Branch will implement strategies that support earlier engagement with industry, patient and consumer groups and other stakeholders in drug development. This will improve the predictability and efficiency of the regulatory review process for clinical trial applications and new drug submissions. The Branch will also support scientific research in emerging technology areas such as medical devices, genetic therapies and novel drug delivery systems to inform regulatory guidance to industry and review practices.

### ***Key performance indicators:***

- *pre-market submissions are reviewed within performance targets*
- *modernized legislative tools, policies and regulatory approaches have been developed and implemented*

## Strategy 2: Providing Authoritative Information for Healthy Choices and Informed Decisions by Canadians

An important way for governments to improve the public's overall health and well-being is to support them in their efforts to manage their own health through informed and healthy choices. This requires providing reliable information, not only about health products, food and nutrition, but also about the regulatory process itself and how and why decisions are made.

As new foods and therapeutic products enter the Canadian marketplace, consumer demand for more and better information about the risks and benefits associated with them will grow.

Providing authoritative and trustworthy information is vital from a public health perspective too. In particular, federal, provincial and territorial governments in Canada are concerned about the increased prevalence of obesity and diabetes, two serious diseases linked to food and nutrition. It is estimated that improved diets and nutrition could reduce coronary heart disease and stroke mortality in Canada by at least 20 per cent and cancer and diabetes mortality by at least 30 per cent.

*Through this strategy, the Branch will deliver the following key results for Canadians:*

### 2.1 Useful and credible evidence-based information on food, health products and nutrition

The Branch will reinforce its efforts to develop and make available useful and credible information based on sound science, so that consumers, patients and health professionals can continue to turn to Health Canada as a reliable source of information.

### 2.2 Improved public awareness and healthy choices

The Branch will make available information to Canadians that supports healthy choices and informed decisions about health products, food and nutrition.

#### *Strategy 2 Highlights*

- Health Canada's dietary guidance, including *Canada's Food Guide to Healthy Eating*, will be revised to ensure that it reflects evolving scientific evidence concerning the relationships between diet and health and continues to promote a pattern of eating that meets nutrient needs, promotes health and minimizes the risk of nutrition-related chronic diseases.
- The Branch will improve product monograph requirements for drugs, including a new consumer information section.
- The Branch will promote awareness about the new nutrition labelling requirements on food and how the labels can be used to make healthy choices.
- The Branch will work with provincial and territorial partners to deliver nutrition programs and services at the community level, including in schools.



## **2.3 Supportive conditions to enable Canadians to make informed and healthy choices**

The Branch will work with federal, provincial and territorial partners, industry, academia, the education system and non-governmental organizations to establish the necessary conditions and capacity to enable Canadians to make informed and healthy choices related to health products, food and nutrition.

## **2.4 Strategic and coordinated communications**

The Branch will ensure that its internal and external communications are well coordinated, strategically managed and responsive to the diverse information needs of Canadians.

### ***Key performance indicators:***

- *consumers and patients are more aware and knowledgeable about health products, food and nutrition issues*
- *consumers and patients are making more informed choices and demonstrating more safe and healthy behaviours relating to health products, food and nutrition*

## **Strategy 3: Increasing Responsiveness to Public Health Issues and Vigilance over Safety and Therapeutic Effectiveness**

The Canadian health system must become more responsive to a range of public health issues. This includes continuing to ensure that the food and health products available in Canada are safe. HPFB is strengthening its capacity to identify and assess the health and safety risks associated with health products and food, apportion responsibility for managing risk appropriately between industry, stakeholders and Canadians, and alert the public to problems when they occur.

In addition to managing health and safety risks, the regulatory system for health products and food must concern itself with product effectiveness, both in terms of value for money and therapeutic benefit. From a public policy perspective, the former helps maintain the affordability of drug insurance plans and control the cost of the public health care system, which in turn promotes public access to health care and therapies, while the latter ensures consumers can make informed decisions based on reliable, useful and sound scientific information. Using the regulatory system to improve product effectiveness demands an approach that links regulation with health system outcomes.

*Through this strategy, the Branch will deliver the following key results for Canadians:*

### **3.1 Improved risk management and communications as a shared responsibility with stakeholders**

The Branch will strengthen its management of product safety-related risks in collaboration with stakeholders. It will improve its ability to communicate risks to patients, the public and health professionals by cooperating more actively with partners, providing industry with explicit guidance on communicating with health professionals and the public, and improving its tools for informing Canadians about food- and nutrition-related health risks.

### **3.2 Improved assessments of health products, food and nutrition based on research and surveillance**

Working with its partners, the Branch will conduct research and surveillance activities to assess the safety, effectiveness, quality, risks and benefits of health products, food and nutrition; monitor exposure to hazards across the country over time; and identify at-risk population groups and products. The information gathered through these activities will guide the development of health product, food and nutritional policies and programs, and support consumer information and education.

### **3.3 Enhanced post-market surveillance of safety and therapeutic effectiveness**

Collecting information on adverse reactions to health products, both in Canada and abroad, alerts regulators to unforeseen risks associated with these products once they reach the marketplace. Through the Therapeutics Access Strategy, the Branch will improve its capacity to collect, analyze and share information about the safety and therapeutic effectiveness of human and veterinary drugs and natural health products available in the Canadian marketplace.

### **3.4 Effective compliance and enforcement**

The Branch will increase the frequency of its compliance and inspection activities to ensure that the health products available in Canada meet Canadian and international standards for safety, quality and efficacy. The Branch will also continue to work with the Canadian Food Inspection Agency, which is responsible for inspection, compliance and enforcement activities related to food products.

#### ***Strategy 3 Highlights***

- The Branch will establish two new regional centres for reporting adverse drug reactions (ADR), increase its focus on ADRs in children and make adverse drug reaction information available to the public in a timely fashion through the Canadian Adverse Reaction Newsletter, expanded website activities, and an automated listserv system.
- The Branch will continue to conduct the Total Diet Study, an ongoing national program recommended by the World Health Organization that measures the levels of potentially toxic chemicals in foods consumed by Canadians.
- The Branch will pursue improved regulatory compliance by industry through increased post-market inspections in adverse drug reaction reporting and human cells, tissues and organs for transplantation.

### 3.5 Integrated role in the health system

The Therapeutics Access Strategy will focus on optimizing the benefits of human drugs in the health care system through appropriate use, including better prescribing practices. This will contribute to a more cost-effective health care system and optimal drug therapy for Canadians.

#### ***Key performance indicators:***

- *more and better tools are available to all partners responsible for risk management and risk communications capacity in the regulatory system (including quality management systems, guidance documents, standard operating procedures)*
- *therapeutic effectiveness evidence is used to support formulary listing decisions for health products*
- *the number of users of Health Canada's MedEffects portal is significant and increasing with time*
- *the number of adverse drug reactions reported to the new regional centres is increasing*
- *industry stakeholders comply with departmental regulations and standards (through the rate and nature of infractions)*

## **Strategy 4: Improved Transparency, Openness and Accountability to Strengthen Public Trust and Stakeholder Relationships**

Incorporating the views of citizens and stakeholders is a critical success factor for regulating effectively in the public interest. An engaged citizenry has implications for governance, ethics, transparency, openness and accountability. Maintaining and strengthening public confidence is especially important in a world where the accelerating rate of scientific and technological advances carries both benefits and risks. Public confidence in the regulatory system, particularly as it applies to health-related products and services, is also a prerequisite for ensuring that new and beneficial health innovations are brought to Canadians and used by them.

Government and industry, as well as patient and consumer organizations, are coming to understand their respective roles in making the regulatory system work for all Canadians. Improving transparency, openness, and accountability and encouraging all stakeholders to share responsibility for this aspect of health product regulation are key objectives of the Branch and the Therapeutics Access Strategy. The 2003 Public Policy Forum consultations with stakeholders on Health Canada's therapeutics review process underscored that the Branch should fully integrate these principles into its business.

*Through this strategy, the Branch will deliver the following key results for Canadians:*

#### **4.1 Increased public accountability through annual performance plans and reports**

Accountability is critical in demonstrating to Canadians how effectively the Branch uses public funds and serves the public interest. Its importance is underscored in both the *2003 Accord on Health Care Renewal* and the *2004 Speech from the Throne*. To ensure that Canadians have easy access to information about its commitments and accomplishments, the Branch will make useful and understandable annual plans and reports on its progress and performance widely available to the public.

#### **4.2 Enhanced transparency by increasing public and stakeholder awareness of the Branch's business and decision-making process**

The Branch will communicate more frequently and effectively with the public and make available more and better information about its decision-making so that stakeholders and Canadians can better understand the Branch's day-to-day operations, decision-making processes, and the criteria and reasoning behind its decisions.

#### **4.3 Improved openness through information sharing and more direct participation in the Branch's decision making**

The Branch will create more meaningful and appropriate opportunities for stakeholders to participate in its decision-making process. This will enable the public to influence the development and implementation of the Branch's policies and programs, ensure that the public perspective and interest are considered, and help maintain public trust and confidence in the regulatory process.

#### ***Strategy 4 Highlights***

- The Branch will establish clear, internationally comparable performance targets for all stages of the regulatory review process for therapeutic products and revise performance measurement approaches to ensure consistency with other leading regulators.
- The Branch will make available to the public information and documents that explain the rationale for the Branch's regulatory decisions to grant market authorization of drugs or medical devices.
- The Branch will develop and implement a public involvement framework that will optimize public understanding of and input into the Branch's decision-making processes.
- The Branch will make the regulatory process more accessible to stakeholders, including patient and consumer groups.

### ***Key performance indicators:***

- *public opinion (including stakeholder opinion) about the Branch's accountability for results and the timeliness and transparency of its regulatory process is improved*
- *public confidence and trust in health products, food and the regulatory system is sustained*
- *stakeholders are more aware of the Branch's business and decision-making processes*
- *more individuals seek access to Branch information online*
- *public involvement in Branch program and policy development, implementation and decision-making is increased*

## **Strategy 5: A Nationally-Based, Flexible Organization That Has the Capacity to Fulfill its Mandate and Priorities in a Changing Environment**

The success of the Branch in meeting the challenges ahead depends on organizational stability and effectiveness. Nearly one-quarter of the Branch's scientific staff will be eligible for retirement before 2007–08. Succession planning measures are key to sustaining our scientific knowledge base, retaining the Branch's corporate memory and maintaining the critical workforce strength needed to meet our regulatory obligations.

The Branch's employees reflect the diversity of Canada and work effectively in both official languages. Strengthening these positive attributes helps support the Branch's efforts to build effective and open relationships with Canadians and stakeholders.

Strengthening quality assurance and management tools, systems and processes on an ongoing basis is essential for managing corporate risks and ensuring that the Branch remains capable of gathering the scientific evidence it needs to act in the public interest.

Better information management and technologies will improve productivity and flexibility by enabling the Branch to share and use information and knowledge more efficiently and effectively.

The rising incidence of public health emergencies combined with heightened concerns about biological and chemical terrorism around the world have underscored for the Branch the importance of strengthening and sustaining its emergency response capacity and its approach to business continuity.

*Through this strategy, the Branch will deliver the following key results for Canadians:*

### **5.1 Strengthened nationally-based capacity for sustainable performance**

The Branch will establish plans and initiatives to strengthen its capacity in science, human resources, relationship building and infrastructure. Through its regional offices, the Branch will ensure that its mandate and regulatory responsibilities are being fulfilled efficiently, effectively and in a manner that is sustainable.

### **5.2 Improved management tools and systems**

The Branch will develop and implement more effective management systems, better tools and the business practices needed to maintain and improve its day-to-day operations.

### **5.3 Strategic management of corporate commitments and obligations**

The Branch has a obligation to meet broader departmental and government corporate commitments. This includes implementing the Sustainable Development Strategy, providing support to litigation, responding to access to information requests and attending to administrative business. The Branch will strengthen its capacity to coordinate and manage these corporate commitments and obligations efficiently and effectively.

### **5.4 Leveraged technology to support a high-performing organization**

The Branch will take advantage of the rapid pace of innovation in the fields of mobile computing and the Internet to make information more broadly and readily accessible to Canadians. The Branch will also implement information management strategies to enhance its ability to respond efficiently and effectively to requests for information. In addition, the Branch will continue to implement best practices in technology to improve its operational productivity and effectiveness.

#### ***Strategy 5 Highlights***

- The Branch will strengthen the use of quality management in the National Capital Region and regional laboratories, and implement an initiative on laboratory accreditation.
- The Branch will reinforce its commitment to respond to access to information requests in a timely and effective manner.
- The Branch will establish a framework, integration plan and service capability for information management and information technology.
- The Branch will conduct a review of the current requirements for making available products used in emergency-related activities or nuclear, biological or chemical terrorism-related activities.
- The Branch will develop and implement a Branch continuity plan, security plan and emergency preparedness plan

## 5.5 Strengthened responses to emergencies

The Branch will strengthen its business continuity planning and emergency response capacity to ensure that key services the Branch provides are available to Canadians when they are needed most.

### ***Key performance indicators:***

- *the Branch has a sustainable and flexible work force through human resources and succession planning*
- *science capacity (e.g. laboratory accreditation, recruitment) in the Branch is improved*
- *the number of workplace health and safety incidents is reduced*
- *the Branch is using systems to track resource use and link it to performance (outputs and outcomes)*
- *the Branch is meeting its immediate and ongoing information management and technology needs (including E-review, program data and directorate feedback)*
- *the Branch has implemented an emergency preparedness plan, Health Canada emergency/crisis communications guidelines, business continuity plan, etc.*



# The Way Forward

To address its challenges and respond to opportunities effectively, the Branch is transforming its current legislative, regulatory and policy platforms and working to continuously improve its management practices and processes. Initiatives such as the Therapeutics Access Strategy help facilitate and accelerate these efforts, so that we continue to meet the evolving needs of Canadians effectively.

The launch of the **Health Products and Food Branch Strategic Plan** is one of a broad range of steps the Branch is taking to achieve greater accountability, transparency and openness in the way it regulates and operates. A **Business Plan** will be produced in spring 2004 to provide more detailed information on how the Branch will deliver on this Strategic Plan during the next fiscal year, including intended results and performance targets and measures. The Branch will also report on its performance to Canadians and its stakeholders through an **Annual Performance Report**.

For more information, please consult the *Health Products and Food Branch* website at:  
**[http://www.hc-sc.gc.ca/hpfb-dgpsa/index\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/index_e.html)**

## Health Products and Food Branch Strategic Planning Framework 2004-07

### Health Canada's Mission:

To maintain and improve the health of Canadians.

### Our Mandate

**HPFB's mandate is to take an integrated approach to the management of the risks and benefits to health related to health products and food by:**

- Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and
- Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.

### Our Strategies

**Strategy 1 –**  
Transforming our efficiency, effectiveness and responsiveness as a regulator

**Strategy 2 –**  
Providing authoritative information for healthy choices and informed decisions by Canadians

**Strategy 3 –**  
Increasing our responsiveness to public health and greater vigilance over safety and therapeutic effectiveness

**Strategy 4 –**  
Improved our transparency, openness and accountability, to strengthen public trust and stakeholder relationships

**Strategy 5 –**  
Building a nationally-based, flexible organization that has the capacity to fulfil its mandate and priorities in a changing environment

### Our Key Results

- Transformed regulatory processes
- A regulatory platform for the 21<sup>st</sup> century
- Expanded collaboration with international organizations
- Leveraged national partnerships
- Enhanced health innovation

- Useful and credible evidence-based information
- Improved public awareness and healthy choices
- Supportive conditions
- Strategic and coordinated communications

- Improved risk management and communications as a shared responsibility with stakeholders
- Improved assessments based on research and surveillance
- Enhanced post-market surveillance of safety and therapeutic effectiveness
- Effective compliance and enforcement
- Integrated role in health system

- Increased public accountability
- Enhanced transparency
- Improved openness

- Strengthened nationally-based capacity for sustainable performance
- Improved management tools and systems
- Strategic management of corporate commitments and obligations
- Leveraged technology
- Strengthened responses to emergencies

### Our Principles

Effectiveness

Efficiency

Transparency

Accountability

Cooperation

### Our Values

Taking Pride in What We Do

Building a Workplace Community

Caring for the People of Canada