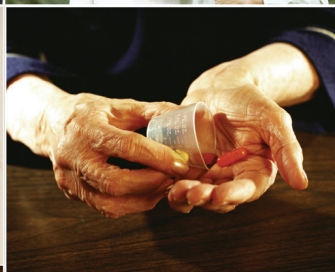


Serving Canadians - Now and Into the Future

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

Overview





***Strategic Plan Overview, 2004–07
Health Products and Food Branch***

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

Health Canada

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Serving Canadians – Now and Into the Future

Health Products and Food Branch Strategic Plan for 2004-2007

Overview

“The broad scope of our mandate means that the work we do touches the lives of every Canadian...Our Strategic Plan is a major milestone in HPFB’s evolution as an organization committed to providing world-class delivery of our mandate and to meeting the needs of our diverse publics.”

Diane Gorman, Assistant Deputy Minister

Canadians expect timely access to safe and effective health products, safe and nutritious food, and the information they need to make healthy choices. The Health Products and Food Branch (HPFB) of Health Canada is a key player in helping Canadians to maintain and improve their health, by minimizing health risks to Canadians and maximizing the safety provided by the regulatory system, promoting the conditions that enable Canadians to make healthy choices, and providing information so that they can make informed decisions.

HPFB’s mandate focuses on managing the risks and benefits relating to health products, food and nutrition. This 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. The Branch ensures 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*.

The work of the Branch rests on a foundation of values supported throughout Health Canada: caring for the people of Canada, taking pride in what we do, and building a workplace community. In its day-to-day operations, HPFB relies on sound science, risk management, and the principles of effectiveness, efficiency, transparency, accountability and cooperation to ensure the best possible service to Canadians.

Globalization, public health trends, and scientific and technological advances have transformed the regulatory environment, and the role HPFB plays in it. Canadians have grappled with the impact of SARS, West Nile virus and bovine spongiform encephalopathy (BSE). New fields, such as biotechnology and nanotechnology, have the power to transform not only our health, but also our physical environment and the way we communicate. The Strategic Plan supports HPFB’s role in contributing to improved health outcomes for Canadians through timely public access to safe, effective and high-quality therapies and health technologies, and quicker identification of risks and benefits associated with health products and food on the market.

Meeting the Health Needs of Canadians

The Strategic Plan identifies five key strategies that will guide the activities of the Branch over the next three years. It will serve as a yardstick against which the Branch will make informed choices about priorities and resources, and establish performance measures. It will also demonstrate the progress the Branch has made in meeting our commitment to serving Canadians more effectively and efficiently, both now and into the future. And it will provide a framework of common understanding for the Branch and its stakeholders.

To continue meeting the health needs of Canadians as we move into the 21st century, the Branch has developed five key strategies to be undertaken over the next three years. The Branch will:

- transform the regulatory system, making it more efficient, effective and responsive;
- provide more authoritative and up-to-date information on drugs, health products, food, and nutrition issues;
- increase its responsiveness to public health issues;
- become more open, transparent and accountable; and
- build a flexible organization designed to achieve its mandate in a rapidly changing environment.

By delivering on these five strategies, HPFB will help all Canadians to maintain and improve their health in a world of fast-paced change.

The HPFB Strategic Plan encompasses the objectives of Health Canada's Therapeutics Access Strategy (TAS). TAS 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 overarching objective of TAS is to improve the health of Canadians through enhanced access to safe, effective, appropriately used, and affordable therapies. The strategy is a comprehensive set of linked measures dealing with innovation, modernization of regulatory regimes, and a strengthened focus on real world safety, therapeutic effectiveness and sustainable access to therapeutic products.

HPFB works collaboratively with partners and stakeholders in Canada and internationally to help Canadians to maintain and improve their health. 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.

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

Globalization, the rapid evolution of science and technology, and the speed of innovation, mean that the regulatory system must be ready to maintain safety while ensuring that Canadians have continued access to the latest in health products, foods, new therapies and health technologies, both from Canada and from around the world. This can only be achieved when all levels of government work together, in a climate of international regulatory cooperation. Under Strategy One, HPFB will:

Key results:

- transformed regulatory processes
- a regulatory platform for the 21st century
- expanded collaboration with international regulatory authorities
- leveraged national partnerships
- enhanced health innovation

- 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;
- implement Good Guidance Practices to help industry improve the quality of submissions, as well as Good Review Practices to ensure high quality reviews;
- develop an international regulatory cooperation strategy; and
- develop a national food safety strategy with the Canadian Food Inspection Agency, Agriculture and Agri-Food Canada, and provincial and territorial partners.

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

Canadians manage their own health best when they can make decisions and choices based on reliable information, including details on how and why regulatory decisions are made. This issue is critically important now, with the increased prevalence of obesity and diabetes in Canada, two serious health issues linked to food and nutrition. As part of its strategy to provide more useful, evidence based information, HPFB will:

Key results:

- useful and credible evidence based information
- improved public awareness and healthy choices
- supportive conditions
- strategic and coordinated communications

- revise Health Canada's dietary guidance, including *Canada's Food Guide to Healthy Eating*, 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;

- improve product monograph requirements for drugs, including a new consumer information section; and
- promote awareness about the new nutrition labeling requirements on food and how the labels can be used to make healthy choices.

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

HPFB must identify and assess health and safety risks, as well as alert the public to any problems. It also has to consider the therapeutic effectiveness of health products and food. In order to strengthen our responsiveness and vigilance, HPFB 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 web subscription system;
- continue to conduct the Total Diet Study, an ongoing program recommended by the World Health Organization that measures the levels of potentially toxic chemicals in food consumed by Canadians; and
- pursue improved regulatory compliance by industry through increased post-market inspections focussed on adverse drug reaction reporting and human cells, tissues and organs for transplantation.

Key results:

- 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

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

To work effectively in the public interest means that the views of citizens and stakeholders must be taken into account, especially when both the benefits and the risks of scientific and technological advances are accelerating so quickly. Government, industry, health care professionals and patient and consumer organizations all share responsibility for making the

Key results:

- increased public accountability
- enhanced transparency
- improved openness

system work, and for being more open, transparent and accountable. This is a key objective of the Branch, and the focus of its activities under the Therapeutics Access Strategy.

In order to fully integrate these principles, and increase public confidence, HPFB will:

- establish clear, internationally comparable performance targets for the regulatory review process for therapeutic products;
- make information and documents available to the public that explain the rationale for the Branch's regulatory decisions to grant market authorization of drugs or medical devices; and
- make the regulatory process more accessible to stakeholders, including patient and consumer groups.

Strategy 5: A Nationally-Based, Flexible Organization that has the Capacity to Fulfill its Mandate and Priorities in a Changing Environment

In order to fulfill its mandate of protecting the public interest in a rapidly changing environment, the Branch will focus on a number of measures to improve its capacity and infrastructure. These include succession planning measures, especially in the scientific field, building open relationships with Canadians and stakeholders, strengthening quality assurance and management tools, systems and processes, using better information management and technologies, and strengthening and sustaining its emergency response capacity. Specifically, HPFB will:

Key results:

- 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

- strengthen the use of quality management in the National Capital Region and regional laboratories, and implement an initiative on laboratory accreditation; and
- conduct a review of the current requirements for making available products used in emergency related activities or nuclear/radiological, biological or chemical terrorism related activities.

Moving 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 can continue to meet the evolving needs of Canadians effectively.

For more information on the work of HPFB and for more detail on the strategies discussed in this Overview, please consult *Serving Canadians - Now and Into the Future: The Health Products and Food Branch Strategic Plan for 2004-07* or our website at:

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 21st 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