



## **Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food**

**For discussion purposes only  
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## Introduction



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

I am pleased to present Health Canada's approach to modernizing the regulatory system for health products and food.

Health Canada's existing regulatory approach has evolved slowly and incrementally over the past 50 years. Throughout this period, adjustments were made to meet changing circumstances. While it has served Canadians well, the regulatory system is challenged by diverse social, economic, scientific and technological developments. The current legislative and regulatory tools no longer adequately support Health Canada's response to these pressures. This new context requires a reorientation of the regulatory system to better align with modern realities.

Over the years, Health Canada has made strong progress to modernize the regulatory system. Most noticeably, the Therapeutics Access Strategy, launched in 2003, has led to significant gains in the efficiency and responsiveness of our product review system. We have eliminated our review backlog in pharmaceuticals and biologics. We are now meeting internationally-comparable review performance targets for pharmaceuticals and are on track to meet them for biologics by March 2007. We have also implemented new measures to strengthen the safety of the regulatory system and made significant progress in increasing the transparency and openness of our regulatory activities.

This recent progress marks a great achievement for the Branch and presents a new opportunity to talk about the future.

This Blueprint for Renewal is intended to initiate a dialogue to guide the modernization of the Canadian regulatory system and achieve a vision as an internationally recognized regulatory leader. Central to this vision, Health Canada will need to have an adaptable and sustainable regulatory system that:

- helps Canadians improve their health outcomes through timely access to safe, effective and high-quality health products and food;
- strengthens safety oversight through a product lifecycle approach;

- sustains and improves regulatory efficiency and predictability, while maintaining Health Canada's high standards for safety;
- is accountable, open and transparent to stakeholders and the public; and
- contributes to better aligned regulatory and reimbursement decision making.

Our primary goal in the development and implementation of the Blueprint's vision will be the protection of the health and safety of Canadians.

This is a long-term vision and will require time and effort to be fulfilled. As our regulatory mandate spans from the research and development environment to the health system and access by Canadians to health products and food, this modernization will necessarily have broad impacts and will require not only your input, but your cooperation. Many partners play a role in supporting the health and safety of Canadians. I look forward to hearing your views.

## Health Canada's Blueprint for Renewal – A snapshot

### Vision

As an internationally recognized regulatory leader, Health Canada will have an adaptable and sustainable regulatory system that

- helps Canadians improve their health outcomes through timely access to safe, effective and high-quality health products and food;
- strengthens safety oversight through a product lifecycle approach;
- sustains and improves regulatory efficiency and predictability, while maintaining Health Canada's high standards for safety;
- is accountable, open and transparent to stakeholders and the public; and
- contributes to better aligned regulatory and reimbursement decision making.

### Our Mandate

To take an integrated approach to the management of the risks and benefits related to health products and food by:

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

### Objectives

- ➊ 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.
- ➋ Health Canada will move toward a more transparent and consistent system of categorizing products and assessment of their risks.
- ➌ 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.
- ➍ Health Canada will move the regulatory system away from a reactive "waiting for events" system to a proactive approach that engages stakeholders and helps influence the future, today.
- ➎ 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.
- ➏ 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.
- ➐ 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.
- ➑ Health Canada will work to better synchronize the regulatory system with the objectives, policies and practices of the health care and innovation systems.

## Part 1 What do we want to be?

Health Canada’s Health Products and Food Branch is Canada’s federal authority responsible for the regulation of health products and food. The Branch:

- evaluates and monitors the safety, quality and efficacy of health products (such as drugs, vaccines, medical devices, natural health products and other therapeutic products) available to Canadians, as well as the safety and nutritional quality of the foods they eat;
- protects human and animal health and the safety of Canada’s food supply by evaluating and monitoring the safety, quality and effectiveness of veterinary drugs, setting standards, and promoting the prudent use of veterinary drugs administered to food-producing animals and companion animals; and
- promotes the health and well-being of Canadians through a broad range of activities related to health products and food, including developing nutrition policies and standards such as *Canada’s Food Guide to Healthy Eating*.

### Did you know?

Number of human drug products currently available to Canadians: **over 22,000**

Number of medical devices: **40,000**

Number of biologics and genetic therapies: **400**

Number of natural health products: **42,000**

Number of veterinary drugs: **1,450**

**28** categories of food and more than **400** food additives

Health Canada is committed to serving Canadians both now and into the future, by continuing to strengthen its position as a nationally recognized and world-class regulator. This requires

- sustaining effective regulatory tools and promoting innovative solutions to new population and public health policy challenges, where appropriate;
- emphasizing effectiveness and efficiency, and more fully integrating evidence-based decision making;
- influencing and adopting internationally respected scientific advice and internationally recognized regulatory best practices, and pursuing international regulatory cooperation opportunities;
- meeting high standards of vigilance over “real-world” product safety and effectiveness; and
- promoting a culture of openness and transparency.



The world has changed substantially since the passage of the *Food and Drugs Act* over 50 years ago. Building on progress made under the Health Product and Food Branch's *Strategic Plan 2004-07*, Health Canada recently began a comprehensive renewal of its regulatory system. By addressing key challenges and opportunities affecting Canada's regulatory environment, Health Canada can better serve Canadians now and into the future.

This document articulates our Blueprint for Renewal: the case for renewing Canada's regulatory system (Part 2); progress made to-date (Part 3); the eight objectives of the Blueprint (Part 4); the critical success factors (Part 5); how Health Canada will measure progress and strengthen accountability, as well as the next steps (Part 6). The Annex section includes additional information on a number of specific initiatives that are being developed under the Blueprint umbrella.

## Part 2 Why change our regulatory system?

### The case for renewal

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 embodied in the Act and its regulations were designed to meet the challenges of the day. The Act was largely intended to be a consumer protection statute.

This has had longstanding implications for the role of the regulator. This role was primarily concerned with providing citizens and regulatees with some level of “fair play” within the market for the manufacturing and marketing of food and drugs. However, many things have changed since the 1950s, including the view of citizens 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. 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

#### Did you know?

The *Food and Drugs Act* is an Act of Parliament regarding the manufacture; import; export; transport across provinces; and sale of food, drugs, medical devices, and cosmetics (including personal cleaning products such as soap and toothpaste). The Act sets out the requirements for the safety and efficacy of products and the disclosure of their ingredients, and ensures that drugs are not sold as food or cosmetics.

informed and engaged citizenry;

- a regulatory system that currently works in isolation from the activities and policies at the stage of research and development, and those of the broader health care system; and
- a regulatory system with insufficient resources for long-term efficiency and sustainability.

### **A limited and inflexible regulatory toolkit**

Health Canada's regulatory framework for health products is imbalanced towards pre-market assessment, meaning that post-market surveillance to detect emerging risk signals is hampered by a lack of authorities. For example, there is little regulatory flexibility for assigning conditions to market authorization licences or granting emergency use for unlicensed products. This is of particular concern at a time when recent events, such as the global withdrawal of Vioxx, have heightened public concerns around safety and revealed limitations in Health Canada's capacity and authorities.

Moreover, once a product is authorized for market, Health Canada's regulatory and policy levers to obtain new safety information, as well as to monitor whether products are used as intended, are limited. Health Canada lacks the authority to compel additional safety, efficacy and effectiveness studies as a condition of continued marketing or when new information suggests that additional research is warranted. Its authorities for compliance and enforcement, based on criminal law, are outdated and resource intensive, which limits the range of actions that can be taken, including appropriate sanctions and incentives.

Similarly, the current legislative framework and regulatory instruments increasingly lag behind more modern concepts concerning the confidentiality of commercial information. Scientific and technical innovation requires a regime that protects intellectual property rights. But the public interest now requires that these protections be balanced with the need to make sufficient information available to enable meaningful citizen engagement and foster informed choice. At the same time, advances in genomics raise new issues relating to the protection of personal health information and privacy.

#### **Did you know?**

Some recent events affecting all Canadians that Health Canada is working to address:

- public concerns about the safety of products on the market;
- an increasing number of class action lawsuits related to health products;
- allegations of industry non-disclosure of negative clinical trial results;
- adverse reactions in off-label use of anti-depressants in children; and
- the public health risks of using veterinary drugs inappropriately.

In addition, Health Canada must still use mandatory consultative processes (i.e., the *Canada Gazette* process) to make many of the most basic rule-making changes for approved regulatory submissions. More agile, risk-based systems (using a variety of regulatory tools) could be used to make quick technical, administrative or anticipatory changes to the regulatory framework without decreasing transparency or creating a burden for patients, industry and government. For example, Health Canada is required to undertake a full regulatory amendment process to approve new uses for existing and approved food additives, to establish Maximum Residue Limits (MRLs) for veterinary drugs, and to add or remove medicinal ingredients from Schedule F of the *Food and Drug Regulations*. This approach is time- and resource-intensive and is often not commensurate with scientifically established risk.

Reliance on outdated regulatory instruments also has repercussions for Canada’s ability to undertake international regulatory cooperation initiatives or to harmonize its regulatory regime with those of other jurisdictions. Health Canada requires regulatory tools that support, rather than hinder, its ability to fulfil its health protection and promotion mandate.

### **Reconsidering the regulatory paradigm**

Increasingly, Canada’s approach to the regulation of health products and food is out of step with international best practices and, more fundamentally, with the needs and expectations of Canadians. It is generally a passive system that is activated by events, rather than influencing outcomes. There is an imbalance between pre-market and post-market activities, and lack of a coherent and effective approach to pre-market evaluation for food products. It relies on a point-in-time approach to product approvals and is not designed to address “real-world” product safety and effectiveness. Taken together, these challenges suggest a need to fundamentally change our regulatory approach as a necessary prerequisite to meet the rising expectations of Canadians.

In its 2004 report, *Opening the Medicine Cabinet: First Report on Health Aspects of Prescription Drugs*, the Standing Committee on Health recommended that “Health Canada make licensing of new

#### **Did you know?**

Some side effects or benefits of health products only emerge after a product is on the market. This is often because there is a larger patient population in the real world than in a clinical trial.

drugs probationary to ensure that post-market surveillance of adverse drug reactions is carried out diligently during a specified period after the drug is approved for marketing.”

Canadians value choice, expect safe and high-quality health products and food, and are increasingly looking for information on the health benefits and risks of products. Modern regulators benefit from being more open, transparent and accountable in their decision making.

In modernizing the regulatory system, Health Canada will need the capacity to effectively anticipate and respond to the implications of change to be able to maintain an environment that supports innovation and continues to provide Canadians with safe, effective and high-quality health products and food. Health Canada has an opportunity to promote early engagement and to solidify the roles and responsibilities of partners along the product development cycle - from the research and development stage to the point where these products are used in the “real world”. Health Canada will also need to cooperate with forward-thinking international jurisdictions, so as to maximize benefits for Canadians.

### **The impact of external drivers of social and economic change and advances in scientific knowledge**

Powerful drivers of social and economic change are gaining momentum in Canada and are reshaping its institutions, including the regulatory system, and the health landscape.

Scientific and technological advances hold great promise for improving health, either directly through more effective cures and preventative interventions, or indirectly through improvements in health care systems and physical environments. The proliferation of new technologies requires regulatory regimes that can enable public access to new products while safeguarding public health and safety. Regulators must remain astute predictors of developments in evolving fields and must also have the capacity to evaluate the risks and benefits of increasingly complex products and treatments.

Globalization and increasing regional economic integration are giving rise to new transborder public health and safety issues. For

#### **Some external drivers affecting the Canadian regulatory system**

- a more informed citizenry demanding higher performance standards from their public institutions;
- accelerating scientific and medical advances;
- globalization of trade, increased international travel, rapid population growth in cities, dramatic changes in farming practices;
- rise of transborder health and environmental threats;
- changing demographics; and
- new geopolitical security dynamics.

example, stronger global and regional interconnections can accelerate the speed of transmission of infectious diseases (e.g., Severe Acute Respiratory Syndrome) while, at the same time, increasing the importance of international regulatory cooperation to combat their spread and take preventive measures.

Supporting a healthy international trade environment for food and protecting the health and safety of Canadians requires an ability to anticipate and adapt to emerging health and food safety issues, such as Bovine Spongiform Encephalopathy (BSE) or genetic modification of organisms and food. In addition, major concerns for the health of humans and animals have been raised over the inappropriate use of certain drugs used in food-animal production (meat, eggs, milk, and honey), such as antimicrobial resistance and the presence of violative residues in foods originating from animals treated with veterinary drugs. The trust that Canada's international partners have in the quality and safety of Canadian food products is linked to Canada's ability to maintain the integrity and bio-security of our food supply.

### **Improving health outcomes with new advances in technology**

Technological advances in such fields as pharmacogenomics, tissue engineering, nanomedicine and novel functional food products hold promise in achieving improved health outcomes.

### **Isolated regulatory, health, and research and development systems across product life cycles**

Currently, Canada's regulatory, health care, and research and development systems work, in general, autonomously from each other, each one independently advancing specific objectives and interests. As a result, these systems fail to act interdependently at key points through the life cycle of health products - from discovery, to pre-market approval, to commercialization and through to post-market evaluation for safety, therapeutic effectiveness and cost-effectiveness.

Provinces and territories are raising questions about the downstream impacts on the health system of access to unapproved therapies through the Special Access Programme and the basis of market authorization decisions for new drugs (e.g., expensive drugs for Canadians with rare diseases). In general, there is a lack of consistency in how regulatory access mechanisms - the Special Access Programme, clinical trials and market authorizations - are used by patients and physicians. A review of these access mechanisms will be completed to ensure

**Challenges facing governments and health professionals: The case of COX-2 inhibitors**

Safety issues stemming from off-label use, inadequate monitoring and reporting of adverse drug reactions, and over-medication pose a significant challenge for both governments and health professionals. The case involving COX-2 inhibitors offers an example. Participants on Health Canada's Expert Advisory Panel on COX-2s expressed concerns that "most of the twofold increase in the use of anti-inflammatory agents in Canada that occurred immediately after the introduction of COX-2 inhibitors cannot be explained by their use in patients with severe inflammatory arthritis who were previously under-treated."

that they are appropriately used.

As drug use increases with new, more expensive drugs increasingly available, the sustainability of the health system becomes a critical challenge for all governments. According to the Canadian Institute for Health Information, total drug expenditures in Canada are expected to have reached \$24.8 billion in 2005 (17.5% of total health expenditures). Drug expenditures is the fastest growing component of health expenditures in Canada, with an average annual growth rate of about 10% since 1985.

Expanding use results in significant growth in drug plan costs. Furthermore, experts argue that ensuring the appropriate use of these medications will require a concerted effort of regulators, patients, physicians, veterinarians, pharmacists and others.

Expanding public access to drugs should depend on demonstrating that they are safe, have therapeutic benefits that outweigh their risks and are cost-effective relative to other interventions. This demands new and effective models of cooperation and communication between the research community (including industry), health professionals, and regulatory and reimbursement decision-makers in governments.

**Regulatory system efficiency and sustainability**

Public accessibility to safe and effective health products and food will depend on Health Canada's ability to have a sustainable and efficient regulatory system. In Canada, the year 2005 marked the highest number of submissions received for both pharmaceuticals and biologics in the past five years. It also marked a year in which the Canadian regulatory system achieved higher regulatory performance for pharmaceuticals, biologics and medical devices in relation to decisions issued on time, number of reviews completed and reduction in backlogs.

The success of the system will be judged by its ability to deliver programs in a timely, efficient and cost-effective manner, and to use resources responsibly to optimize the value and benefits for Canadians. Adequate resources and capacity will be required to help maintain and improve regulatory performance and the level of in-house scientific expertise, both of which are critical for achieving the vision and objectives outlined in this Blueprint.

## Part 3 What have we done so far?

### Progress to date

#### Did you know?

In its 2004-2007 Strategic Plan, *Serving Canadians - Now and Into the Future*, the Health Products and Food Branch committed to five key strategies to ensure that Canadians have timely access to safe and effective health products, safe and nutritious food, and the information they need to make healthy choices. The Strategic Plan is available online at [www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/strat\\_plan\\_e.htm](http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/strat_plan_e.htm)

#### Did you know?

The review backlogs of pharmaceutical and biologic submissions have been eliminated (in 2005 for pharmaceuticals; as of September 2006 for biologics).

The review backlog for medical devices was reduced by 80% in 2005 compared to the previous year.

In 2005, Health Canada approved 24 new medicines never before available in Canada. Most of these new products are for cancer treatments, but also include drugs for the treatment of HIV infection, diabetes and infertility.

For more information on Health Canada's health product review performance, please consult our 2005 Annual Summary of Performance at [www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/performance\\_rendement\\_2005\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/performance_rendement_2005_e.html)

In 2004, Health Canada's Health Products and Food Branch released its three-year Strategic Plan, "Serving Canadians — Now and Into the Future." The plan represented a major milestone in the Branch's evolution and its commitment to be a world-class regulator. Five key strategies for change were identified in the Plan, and significant progress has been made in each area, as reported below.

#### **Strategy 1: Transforming Branch efficiency, effectiveness and responsiveness as a regulator**

Through the Therapeutics Access Strategy, launched in 2003, the efficiency of the drug review system has been substantially improved. Investments have supported streamlining the pre-market review process so that submissions are being managed as projects, additional scientific review capacity is in place and new tools are being developed to enhance infrastructure in support of more efficient and transparent decision making. Health Canada is now meeting internationally benchmarked performance targets for review of new drug submissions for pharmaceuticals, and is on course to meet them for biologics and genetic therapies by March 2007, without compromising its high standards for safety.

To respond to the demand for safe and effective natural health products, Health Canada developed the *Natural Health Product Regulations*, which came into effect in 2004. Since 2004, over 1,700 natural health products were assessed for safe use and received market authorization -10,000 more were previously authorized under the drug framework with a drug identification number (DIN). In addition, Health Canada's *Guidelines for the Safety Assessment of Novel Foods* (originally published in 1994) have been revised and updated to incorporate internationally established guidance for the assessment of novel foods of microbial and plant origin. The revised guidelines, which are available on Health Canada's web site, will help to improve the quality and completeness of submissions the department receives from industry.



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

Among new initiatives to provide Canadians with the information they need to make healthy choices, Health Canada launched its MedEffect Web site, which provides Canadians with access to the latest advisories, warnings and recalls concerning health products currently on the market. In addition, the Notice of Compliance database has been launched. Canadians are now able to search information about all drugs that have received a Notice of Compliance since 1994. Further, Summary Basis of Decision documents are now being published for all new active substances (biological and pharmaceutical) and certain high-risk medical devices that received market authorization after January 1, 2005.

Health Canada posts, on its Web site, the list of approved food packaging materials, and some decisions and summaries of novel food evaluations, as well as survey results for chemical contaminants such as acrylamide and benzene. Health Canada also continues to promote awareness about the new nutrition labelling requirements for food products and how food labels can be used to make healthy choices.

Health Canada has also been working to revise *Canada's Food Guide to Healthy Eating*. The revised Food Guide is expected to be released in late 2006 or early 2007.

## **Strategy 3: Increasing responsiveness to public health issues and vigilance over safety and therapeutic effectiveness**

In 2005, Health Canada received \$170 million over five years to implement a series of measures to enhance the safety and effectiveness of drugs and other therapeutic products. Work is now under way to:

- strengthen the capacity to review clinical trial applications and monitor and respond to adverse event reports;
- increase compliance and enforcement by strengthening oversight on adverse drug event reporting by manufacturers, research on subject safety and data integrity in clinical trials,

### **MedEffect: Helping Canadians report adverse reactions**

Health Canada's MedEffect Web site now allows health professionals and consumers to report online suspected adverse reactions to pharmaceuticals (prescription and non-prescription), biologics, natural health products, and radiopharmaceuticals.

[http://www.hc-sc.gc.ca/dhp-mps/medeff/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/index_e.html)

and post-market compliance verification; and

- implement a regulatory framework for the safety, efficacy and quality of blood, cells, tissues and organs intended for transfusion/transplantation.

In 2005, Health Canada also established two new regional adverse reaction monitoring offices in Manitoba and Alberta.

#### **Strategy 4: Improved transparency, openness and accountability to strengthen public trust and stakeholder relationships**

Health Canada has made significant progress in increasing the transparency, openness and accountability of its regulatory decision making, with over 100 consultations undertaken each year. For example, in 2005, national consultations were undertaken on the registration and public disclosure of clinical trial information (an e-consultation was also conducted in the summer of 2006), as well as on *Canada's Food Guide to Healthy Eating*. Health Canada also conducted two groundbreaking public forums that enabled public input on regulatory decision making of marketed products (i.e., COX-2 inhibitors, such as Vioxx and Celebrex) and related to product submissions before Health Canada (i.e., silicone gel-filled breast implants).

Recently, the Department created the External Ombudsman's Office to receive concerns and feedback from individuals and organizations about the way Health Canada fulfils its responsibilities under the *Food and Drugs Act*. The Department also continued to pilot a voluntary system for public notification of novel food submissions, which allows for a 60-day public comment period on scientific matters for each new submission.

#### **Strategy 5: A nationally based, flexible organization that has the capacity to fulfil its mandate and priorities in a changing environment**

Health Canada has actively pursued strong partnerships with key regulatory counterparts to facilitate information sharing on the safety and efficacy of health products and food, which enhances our ability to protect the health and safety of Canadians. In 2003, the Health Products and Food Branch signed a Memorandum of

#### **Improving transparency and opportunities for public participation**

To support Health Canada's commitment to serve Canadians through quality decision making, the Health Products and Food Branch has developed a draft *Policy on Public Input into the Review of Health Products*. The Policy promotes the consideration of public input in the review of the safety and effectiveness of a health product, and describes when and how the Branch will seek input.

Understanding (MOU) and Confidentiality Agreement with the U.S. Food and Drug Administration.

Other MOUs were recently signed with:

- Australia's Therapeutic Goods Administration (2004);
- Australia's Pesticides and Veterinary Medicines Authority (2005);
- China's State Food and Drug Agency (renewal of MOU);  
and
- Singapore's Health Sciences Authority (2006).

Other MOUs have also been developed with food regulatory authorities in Australia, New Zealand and the U.K.

## Part 4 How do we get to where we want to be?

### Blueprint for Renewal: Objectives

Health Canada’s Blueprint for Renewal identifies eight areas for action, supported by five critical success factors (see Part 5) that respond to challenges and build on progress to date. These priorities represent areas where Health Canada has a clear mandate to deliver tangible results for Canadians.

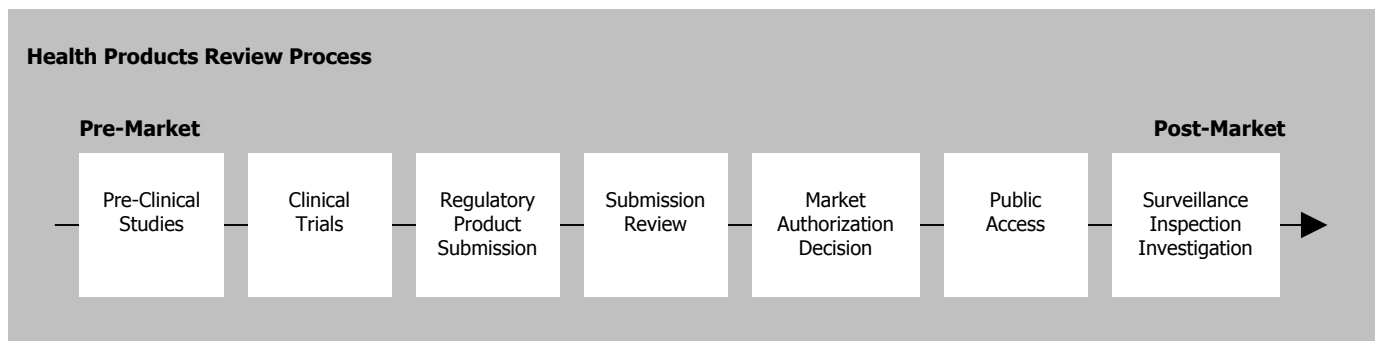
#### 1 Moving to a product life cycle approach

Health products have a “life cycle,” (the “food life cycle” is discussed on the next page) starting with research and development, through to clinical trial Phases I, II and III (where applicable), regulatory approval and market authorization, and use in the “real world.” Increasingly, governments are challenged to provide access to health products at earlier stages of the product life cycle on the basis of limited evidence on their safety, therapeutic effectiveness and cost-effectiveness.

Pressures not only include access to new health products following Health Canada’s market authorization, but also access prior to market authorization through the Special Access Programme and clinical trials. Patients and consumer groups are now better informed about drug development and use, and are increasingly requesting access to experimental drugs that have not been fully tested, but that may offer some hope for patients with debilitating and/or life-threatening medical conditions. Often such patients see the traditional regulatory process as a barrier to access.

**Objective**

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.



Also, Health Canada has currently limited authorities and tools to effectively monitor the safety of products after they have reached the market. New regulatory tools are also required to strengthen compliance and enforcement activities.

A life cycle approach would mark a major shift in regulatory practices. It would allow for a continuous evaluation of the safety, effectiveness and quality of products before and after their introduction to the Canadian market.

New regulatory authorities would allow for assessments performed prior to initial market authorization to continue throughout the market life of the drug, and therefore, take into consideration the increased body of knowledge gained after a product is marketed. This could be done through the introduction of pharmacovigilance plans as a requirement for pre-market submission review, and the linking of pharmacovigilance strategies to a progression in licensing status. This ongoing evaluation will be used to improve therapeutic decision-making and enhance risk management (Annex 1 contains more information on a proposed Progressive Licensing Framework).

Plans for the implementation of new safety reporting policies will take into account not only risk-benefit assessment, but also elements of risk management, risk communication and market intervention. In particular, work completed with members of the International Conference on Harmonization (ICH), such as Periodic Safety Update Reporting (PSUR), pharmacovigilance planning and expedited reporting, are awaiting new authorities to be fully implemented. Reviews of the Special Access Programme and the *Clinical Trial Regulations* have also been initiated.

In the food context, this life cycle approach can be translated into a “food continuum” that spans all the way from agricultural inputs (feeds, veterinary drugs, pesticides) to on-farm production, processing and distribution, through to in-home food preparation. For Health Canada to be an effective food safety and nutritional quality regulator, its policies and practices must recognize that food hazards exist throughout the life cycle, particularly in relation to microbiological or chemical contaminants, and must, for example, establish safe levels of veterinary drug residues (e.g. Maximum Residue Levels) that can be present in foods derived

**Did you know?**

Health Canada is currently reviewing its medical devices program to address issues identified by the Auditor General of Canada in her March 2004 report.

**Objective**

Health Canada will move toward a more transparent and consistent system of categorizing products and assessment of their risks.

**Did you know?**

There is a range of low-risk health products and food that Health Canada regulates, which can be used without a prescription, including: **over-the-counter pharmaceutical products, natural health products, sunscreens, antiperspirants, and toothpaste.**

**Did you know?**

In Canada, medical devices are divided into four classes based on the level of risk associated with their use. Class I devices (e.g., thermometers) present the lowest risk and do not require a medical device license for their sale in Canada. Manufacturers of Class II (e.g., contact lenses), Class III (e.g., glucose monitors) and Class IV (e.g., pacemakers) devices must obtain a medical device license before their products can be legally sold in Canada. As the risk of the device increases, more data is required from the manufacturer to demonstrate that it is safe and effective for its intended application.

from animals.

**② Moving to regulatory interventions proportional to risk**

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 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; inconsistent approaches across regulatory frameworks in terms of standards of evidence, health claims, and risk-based regulatory responses.

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 revamp the product categorization system so that regulatory interventions 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 (see side bar). A similar risk classification system could be applied to other regulatory frameworks where it makes sense (e.g., 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 product sponsors understand how decisions are made and can anticipate the approach that will be taken to review their products.

Concurrently, the Department has initiated an overall review of the *Natural Health Product Regulations*. This review will improve Health Canada's efficiency in implementing the regulations by closing the gaps in definitions and clarifying the interface with other regulatory frameworks under the *Food and Drugs Act* (cosmetics, food, etc.).

Similarly, Canadians and regulatees could benefit from having a regulatory system for food that is able to respond with more precision to the full spectrum of food risks. For example, changes might include being able to impose conditions on use or sale of certain foods or food components which require pre-market approval or notification, or providing a less cumbersome administrative system for reviewing new applications for food additives that are already approved (see below).

### ③ Moving toward a modernized regulatory approach for food safety and nutrition

#### Objective

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 marketplace.

Food and food products constitute a special consideration for Health Canada. Safe and nutritious food, and appropriate physical and economic access to a sufficient supply of calories and nutrients, are amongst the most basic, fundamental and unique determinants of population health. Recognizing this, Health Canada will develop and implement a *Regulatory Modernization Strategy for Food and Nutrition* that will be more effective in meeting the food safety and nutrition challenges facing Canadians, and that will provide clear direction to regulatees on government requirements for market access. This strategy will recognize particular realities associated with food and food product regulation.

As an example, Health Canada is sometimes required by the *Food and Drug Regulations* to allocate resources to evaluate, process, consult on and prepare regulatory amendments for certain low-risk food products. Regulations for food safety and nutrition need to adapt to current thinking in the scientific community about the value of a risk-based approach to regulatory interventions so that limited resources are targeted toward the most significant risks to public and population health.

The modernization strategy will provide the basis for new

**Did you know?**

There are types of food and food products that Health Canada is required to review before they go on the Canadian market:

**infant foods, food additives, and novel foods such as those derived through biotechnology.**

**Objective**

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

**Did you know?**

In March 2006, Health Canada published on its web site a draft guidance document on pharmacogenomics to clarify how and when sponsors should submit pharmacogenomic information.

regulatory and policy frameworks for food safety and nutrition, and will support early action on the following:

- improvements to pre-market regulatory processes for food additives and novel foods to ensure that the food regulatory system manages its resources and expertise in such a way that places maximum time and resource investment in higher-risk food safety and nutrition issues;
- a new regulatory framework that will permit health claims for food that support informed consumer choice and that are truthful, substantiated and not likely to lead to harm to consumers; and
- establishment of flexible mechanisms to list Maximum Residue Levels of drugs used by food producers and veterinarians to meet acceptable food safety standards.

**④ Moving to a proactive and enabling regulatory system**

As technologies continue to evolve and converge, and innovative applications of current technologies are conceived, 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 to outline regulatory requirements for new technologies and clinical research processes. This capacity will: help the system to forecast new applications; stimulate safety and efficacy discussions early in the development process; and enable, rather than create obstacles to, the commercialization of safe and effective products for Canadians.

The regulatory system will continue to adapt to new science and technology. For example, new regulatory frameworks for radiopharmaceuticals, vaccines and subsequent entry biologics (or generic biologics) will be developed. Collaboration with national and international research organizations will be expanded to support the development and validation of biomarkers, which will contribute to a more efficient product development process, as well as their use in clinical practice and real-world safety and effectiveness evaluation.



Health Canada will enhance dialogue with manufacturers during early stages of health product development to flag potential evidence gaps for real-world effectiveness of products and discuss any proposed surrogate end-points for clinical trial studies and their subsequent validation. Scientific advice could be targeted, in particular, to small and medium size research and development enterprises.

Finally, Health Canada will continue its progress in establishing and meeting internationally-benchmarked performance targets for all regulated products, building on recent performance improvements in the review of pharmaceuticals, biologics and medical devices.

### **5 Moving to a system that makes the best use of all types of evidence**

#### **Objective**

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 post-market surveillance of the safety and effectiveness of health products. However, current regulatory resources and tools are focused on pre-market assessments and not on the monitoring of real-world safety and therapeutic effectiveness of health products.

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, such as:

- requirement for sponsors to submit pharmacovigilance plans as part of the pre-market submission review;
- regulatory authority to require sponsors to conduct additional post-market studies;
- collaboration with key stakeholders to develop post-market evidence drawn from well-designed, head-to-head comparisons and large observational studies to improve knowledge of therapeutic effectiveness and real-world safety issues;
- implementation of initiatives to address under-reporting of adverse drug reactions;

- development of active surveillance systems, building on results of a recent paediatric pilot project between Health Canada, the Canadian Paediatric Society and the Women’s Health Centre of British Columbia; and
- increased Health Canada scientific and research capacity to assess safety signals.

Under the National Pharmaceuticals Strategy, federal, provincial and territorial governments have recently taken steps to develop a business case for a national research network of centres of excellence that, in principle, could be used to investigate priority signals of both safety and effectiveness issues, 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 medical incident data on a national basis, including through increased collaboration with the Canadian Patient Safety Institute.

### **⑥ Moving to an emphasis on specific populations**

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 patient or genetically specific populations.

In the context of food, important considerations related to the unique vulnerabilities of specific populations - children, seniors, Canadians with celiac disease, the immuno-compromised, Canadians with food allergies - are already part of the safety

#### **Objective**

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.

#### **Did you know?**

For drugs for some rare diseases, it is difficult to gather reliable evidence for safety and efficacy due to low patient numbers.

evaluations and risk assessment for foods. But these considerations will need to be more closely integrated with developments in science and technology and regulatory activities aimed at accommodating food product innovation.

Progress has been made to increase the emphasis on the specific needs of children, such as through the recent establishment at Health Canada of an Office of Paediatric Initiatives. A regulatory amendment has also been proposed by the Government of Canada to extend data protection by six months for products that will be the subject of paediatric trials.

Health Canada is currently establishing two paediatric expert advisory committees (one for policy advice and another for scientific/technical advice) to guide the department regarding future directions. This process will also be used as a model for the department to engage others on regulatory issues for specific populations in the future.

Finally, in the context of its progressive licensing initiative, Health Canada will consider evidence-based mechanisms to enable earlier access with improved safety to health products that address unmet health or therapeutic needs.

### **7 Moving to increased transparency, openness and accountability**

#### **Objective**

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 be more aware of and participate in decisions that may affect their health. This trend is seen not only in Canada, but in most other industrialized countries.

Transparency and openness are fundamentally good regulatory practices that enhance the quality of regulatory 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 develop strategies to more effectively manage information related to health products and food (e.g., through improvements to Health Canada's adverse drug reaction reporting

**Did you know?**

The publication of Summary Basis of Decisions marks the first time all Canadians have access to the considerations that went into Health Canada’s decision to grant market authorization for a drug or medical device.

**Objective**

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

**Working collaboratively for the health of Canadians**

Health Canada and the Canadian Agency for Drugs and Technologies in Health (Common Drug Review), an independent not-for-profit organization, have a pilot project to share information on their respective reviews of new drugs.

and information systems).

Health Canada will also continue to use innovative methods and implement measures, such as:

- a policy to guide consideration of public input in its regulatory decision making on health products;
- enhanced public access to information on clinical trials and their results; and
- improved access to information regarding the basis for regulatory decisions on newly approved products (ie., Summary Basis of Decision documents).

**8 Moving to an integrated system**

Health Canada works collaboratively with partners and stakeholders in Canada and internationally. Many individuals and organizations share responsibility for the health of Canadians. They include the provinces and territories, health researchers, health care providers, industry and Canadians themselves. To better fulfill its regulatory responsibilities, Health Canada needs to develop clear roles and responsibilities with other players. This will help to maintain independence of the regulatory system while moving to a more focussed cooperation agenda, 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 foods, drugs, medical devices and other therapeutic products. The National Pharmaceuticals Strategy directly and indirectly involves the regulatory system, including areas of focus 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 toward a more integrated system, Health Canada will be developing stronger partnerships with a number of organizations, such as:

- improving communication and partnership with the Common Drug Review, including through information sharing and joint discussions with industry on validation of surrogate endpoints and requirements for post-market studies;

- 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 those of other nations or international organizations (e.g., World Health Organization, International Conference on Harmonization, Codex Alimentarius).

Relationships between federal, provincial and territorial governments and food producers associations also exist in the food safety and nutrition context. 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. Health Canada will continue to work with key partners to advance renewal objectives in the area of food and nutrition.

## Part 5 What do we need to get there?

### Critical success factors

In order to achieve the objectives of the Blueprint for Renewal, Health Canada will focus on five key success factors:

- a 21<sup>st</sup>-century toolkit - legislation, regulatory frameworks and instruments;
- internationally benchmarked regulatory practices, processes and risk management;
- a sustainable, high-performance, science-based organization - continued investments in staff and infrastructure;
- strategic international regulatory cooperation; and
- enhanced partnerships and stakeholder involvement.

### A 21st-century toolkit - legislation, regulatory frameworks and instruments

A major initiative is under way for proposed revisions to replace the *Food and Drugs Act* and a variety of other statutes related to product safety and consumer protection. Consultations were held in 2003 and 2004 regarding the proposed changes to modernize the Act, and work has proceeded within Health Canada to develop new legislation under the Legislative Renewal initiative. Updating legislative authorities will allow Health Canada to better manage the risks of products across their life cycle, increase transparency and openness, keep pace with changing science and consumer expectations, and harmonize with other countries.

A broad array of instruments is also available for governments to further public policy objectives and could be applied across the product life cycle. These instruments need to be selectively applied, depending on their appropriateness for achieving the vision and objectives outlined in this 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 its commitment to achieving the greatest benefit for Canadians, Health Canada will assess a range of tools, based on effectiveness, legality, compliance, fairness and socioeconomic impacts, prior to selecting the appropriate instrument. Further details on specific initiatives are found in the Annexes.

### **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. Health Canada will meet performance targets for all regulated products through increased 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.

The science and risk management capacity of Health Canada will be strengthened by identifying key knowledge domains and anticipating trends in their development. The science and risk management capacities are defined by the business processes that support the gathering of evidence, generation of new knowledge and a rigorous approach to decision making. The goal is to use the best available, high quality evidence in support of decisions.

### **A sustainable, high-performance, science-based organization—continued investments in staff and infrastructure**

The nature of scientific evaluation in Health Canada demands a committed and internationally recognized expert staff, as well as high performance standards. The expected demand for trained evaluators/regulators to meet current and future departmental needs exceeds, and will continue to exceed, the availability of such expertise in the marketplace. Consequently, there is added pressure on the department to invest in the resources needed to

**Did you know?**

Science in the Health Products and Food Branch covers all aspects of Canadian food, drugs, medical devices, natural health products and nutrition and requires the expertise of many. Staff include from the laboratory researcher to the scientists reviewing new health product submissions to the inspectors in the regions and the researchers generating the evidence base to create appropriate policies.

attract, develop and retain talented science and technology personnel and support them in the performance of consistently excellent work.

The focus will be on enhancing the scientific quality of regulatory decision making and risk assessments, information technology capacity, laboratory infrastructure, and adequate resources to seek external advice and disseminate information to Canadians.

Scientific expertise will need to be complemented with personnel who are well-versed in risk management and who have the ability to communicate information regarding health products and food to health care practitioners and the public.

Health Canada staff must also be supported by up-to-date information technology infrastructure and research facilities that do not pose barriers to high-quality work. These investments are particularly important to: attract high-quality researchers; communicate and work with national, international and industry partners; and provide accurate information to Canadians. Health Canada will also develop external partnerships with academia and key federal/provincial and international experts and organizations on key scientific issues, such as the development, use and validation of bio-markers.

Health Canada will seek to secure sustainable investments and capacity; promote a culture of transparency and openness; and improve and sustain timeliness, efficiency and responsiveness of the regulatory process, including the use of advanced systems for electronic submission filing and, where appropriate, coordination of single-window submissions.

**Strategic international regulatory cooperation**

International regulatory cooperation is regarded as a pillar of modern regulatory systems. It can promote sound, science-based risk management by facilitating the sharing of scientific and technological data and information, resulting in improved regulatory practices. It can increase Health Canada's ability to cope with fast-paced technological change and potential risks associated with new technologies. Collaboration with regulatory counterparts and multilateral organizations ensures that our health-related activities are of high quality, current and consistent



with similar international efforts.

Through information sharing with regulatory counterparts, the regulatory system can anticipate, assess and prepare a Canadian response to global health trends and issues, such as avian influenza. In addition, international regulatory cooperation activities, including technical assistance and capacity building, can contribute to mitigation of health risks in countries with developing regulatory systems, thus protecting the health of Canadians from dangers associated with imported products or diseases originating from other countries.

Health Canada will approach international cooperation strategically by focussing resources on:

- developing agreements and arrangements with regulatory counterparts and multilateral organizations that are leaders in specific regulated areas. This includes collaboration with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), with the Australian Pesticides and Veterinary Medicines Authority (APVMA) on veterinary drug submission evaluations, and with China on natural health products, for example;
- participate and implement global guidelines and standards; review scientific basis for differences in standards with other countries and revise if appropriate;
- targeting work-sharing activities that enhance the quality and efficiency of domestic decision making. (e.g., parallel or joint reviews with other regulatory authorities);
- promoting openness and transparency of initiatives by involving Canadian stakeholders before international standards negotiations;
- establishing priorities and clear accountability for international regulatory cooperation initiatives; and
- approaching technical assistance and capacity-building initiatives through cost-effective channels, such as the Global Cooperation Groups of the International Conference on Harmonization (ICH), as well as VICH (for veterinary medicinal products), Codex Alimentarius, the Global Harmonization Task Force (GHTF - for medical devices), and

the Pan American Network for Drug Regulatory Harmonization (PANDRH).

### **Enhanced partnerships and stakeholder involvement**

A major transformation of the regulatory system cannot take place without support from its partners and the public. Establishing key collaborations with organizations with complementary mandates will be critical to leverage or supplement in-house capacity and expertise. In particular, partnerships or information-sharing arrangements with the Canadian Institutes of Health Research and the Canadian Agency for Drugs and Technologies in Health, respectively, will better integrate the research and development system with that for health care delivery. As Health Canada has limited capacity and authority to directly generate new evidence, programs that join national research bodies and academic centres with those in the health care delivery system could be beneficial to address mutual priority challenges.

Incorporating the views of citizens and stakeholders is also needed to regulate effectively in the public interest. Public input can result in better regulatory decisions. Maintaining and strengthening public confidence is especially important in a regulatory context, where the actions and decisions taken by governments have real effects on the lives of Canadians and on their ability to manage their health. Stakeholders want effective mechanisms to ensure they are appropriately informed and involved. As a result, Health Canada recognizes the fundamental importance of public involvement and continues to build the knowledge and capacity to support it.

Health Canada will engage stakeholders on an ongoing basis so that their views and perspectives are appropriately taken into consideration at all stages of the development and implementation of the Blueprint. Engagement and collaboration with stakeholders will be part of doing business.

#### **Did you know?**

There are many players involved in the access of health products on the Canadian market:

- The Patented Medicine Prices Review Board,
- provincial and territorial governments,
- the Canadian Agency for Drugs and Technologies in Health,
- health professionals and practitioners, and
- industry.

## **Part 6 Measuring progress, strengthening accountability and next steps**

Over the last 50 years, emerging science and technology have increasingly been manifested in new products, and have contributed to the evolving nature of what is considered “safe” and “effective.” A modern regulatory system for health products and food that keeps pace with these changes must be adaptable and sustainable, now and in the future.

### **Engaging Canadians**

However, the responsibility for developing a strong regulatory system does not lie solely with the government. Everyone has a part to play in realizing the vision.

Modernizing the regulatory system will have an impact on all Canadians - including those in the research and development community, patients and consumers, and those working in health care delivery. Health Canada will engage all concerned stakeholders regarding the roles and responsibilities of each participant - from industry to practitioner to consumer.

As a first step, we are seeking your input on this Blueprint. More specifically, let us know:

- Does the vision paper adequately outline the “case for change” and the limitations of the current regulatory system in terms of maximizing health and safety outcomes for Canadians?
- Do the objectives adequately address the issues facing the regulatory system for health products and food?
- Is the proposed Blueprint for Renewal adequate to develop and implement the long-term vision? Is it either too ambitious or not transformative enough?
- Have we missed anything?
- Are there other areas of focus that you think should be included as we move forward?
- What can you do to help us move forward?

We have developed an electronic workbook to assist you in providing us with your feedback on the Blueprint. The electronic workbook can be accessed at [www.healthcanada.gc.ca/hpfb-blueprint](http://www.healthcanada.gc.ca/hpfb-blueprint)

### **Thematic Consultations**

In addition to seeking Canadians' views on the overall plan articulated in this Blueprint, Health Canada will also be launching a number of thematic consultations over the coming months and year on many of the initiatives described in the Annexes, such as on: the proposed progressive licensing framework for pharmaceuticals and biologics; and the proposed regulatory framework for food-related health claims.

### **Reporting to Canadians**

Health Canada will publish periodic reports outlining progress on the Blueprint for Renewal. This information will be available at [www.healthcanada.gc.ca/hpfb-blueprint](http://www.healthcanada.gc.ca/hpfb-blueprint). We look forward to working with Canadians in our efforts to increase safety, strengthen transparency and openness, and enhance access to safe and effective products through a modern regulatory system that is ready to meet the challenges of the 21<sup>st</sup> century.

## Annexes

### Annex 1

#### Progressive Licensing Framework

The objective of the Progressive Licensing Framework is to develop a regulatory framework that will provide Canada with instruments for modern and innovative regulation of drugs. It will enable Health Canada to be a leader in providing health professionals and patients with the most current and accurate information about drugs so that they can make the most informed decisions possible.

The framework will include a regulatory amendment package to the relevant divisions of Part C of the *Food and Drug Regulations*, and an integrated, risk management approach to licensing pharmaceuticals and biologics. Health Canada will develop new regulations and guidances for the following:

- initial market authorization of pharmaceuticals and biologics in Canada, for innovative, subsequent entry and second-entry (generic) products, including requirements for paediatric studies, when applicable;
- product labelling, content and updating when necessary;
- maintaining market authorization;
- risk management and risk communication measures, as new information on the use of products arises after the time of first marketing;
- a graduated system for enforcement and compliance;
- market authorization conditions, such as post-market study commitments, pharmacovigilance plans; and
- accessing products that will meet unmet medical needs and closely tied to the Special Access Program review.

**Consultations.** There will be extensive consultations beginning in Fall 2006 to engage stakeholders on their values and needs for a drug licensing framework. After the consultations, the Branch will begin drafting a new regulatory framework in Winter 2006-07. This will be followed by further consultations on the framework and a staggered implementation over several years.

## Strengthening post-market safety and effectiveness

Post-market safety is the shared responsibility of regulators, manufacturers, health care professionals, consumers and researchers. It involves assessing new information obtained after market authorization and identifying real-world risks of using therapeutic products. Regulatory bodies balance the oversight of safety and effectiveness by thoroughly assessing therapeutic products before market authorization and by monitoring new information after market authorization.

Health Canada's performance in pre-market review has improved. The Department has cleared its review backlogs of pharmaceutical and biologic submissions and the time difference in getting a drug to market between Canada and other jurisdictions is decreasing. One consequence is that Canada will no longer have access to existing international post-market information before authorizing a product to be sold on the Canadian market and will need to rely more on proactive post-market surveillance systems. The move towards a life-cycle approach is important to improve our understanding of real-world safety and effectiveness, to support early risk detection and to increase the safety of products used in Canada.

To strengthen its monitoring of real-world safety and effectiveness, Health Canada will invest in four areas of post-market surveillance:

**Modern enabling policy instruments.** Support a more integral role for manufacturers in post-market safety by developing new policy instruments; assess the role, value and relative contribution of various policy instruments to improve their use in the monitoring and surveillance of various safety risks; and enable the gradual development, collection and analysis of safety and effectiveness information as the use of health products is expanded and increased after market authorization.

**Enhanced knowledge base.** Exploit new and existing sources of information on safety, effectiveness and usage information, and use state-of-the-art information technology to gather knowledge.

**Pro-active risk evaluation.** Strengthen the risk prioritization process to ensure the timely response to risks and safety threats and to move towards risk prevention and avoidance.

**Knowledge transfer.** Build on Health Canada's highly-regarded risk communication process and facilitate a knowledge-sharing culture and a network of partners with complementary responsibilities for health product safety.

Health Canada is modernizing its post-market capacity through the progressive licensing framework, the National Pharmaceuticals Strategy, legislative renewal, and other initiatives designed to improve the monitoring of real-world safety and effectiveness. Building on recent investments in expertise development, the proposed modernization activities will provide resources to strengthen the post-market regulatory framework and to implement a more comprehensive investigative capacity.

## Legislative renewal

Health Canada is modernizing its legislative framework for health protection built a generation ago. While the current framework has served Canadians well, the Government of Canada is seeking new legislation that will update and integrate existing laws into a more coherent, comprehensive and flexible system. Health Canada expects legislative renewal to support a long-term approach to health protection into the next generation.

Some of the areas under the health protection legislation include food, drugs, therapeutic products, natural health products, consumer products and cosmetics. Health Canada is reviewing legislation such as the *Food and Drugs Act* (1953), the *Hazardous Products Act* (1969), and the *Radiation Emitting Devices Act* (1969). These acts address the health risks to Canadians before the risks lead to injury or disease.

Legislative renewal has been led by the Health Policy Branch of Health Canada, with close collaboration with the Health Products and Food Branch and others in the federal health portfolio. One of the key issues for legislative renewal is to increase responsiveness to the sensitivity of information about health products and food, consultations, and other communications. The updated legislation will support the increased demand for openness and transparency in public processes, including ensuring that new products are assessed in a way that is predictable and transparent to the scientists that develop them, to the businesses seeking to market them, and to the consumers who use them.

The new legislation will also respond to changes that scientific development has created in the range and types of products on the market; to products still in development; and to products to be developed in the coming generation. The policy work for legislative renewal will help the Department respond more broadly to how a product is categorized. The Health Products and Food Branch is committed to reviewing product categorization and related regulations, as well as its own administrative policies and processes. Product categorization will examine a number of options to assess the risk and hazard of each product, and to protect the health of Canadians.

**Consultations.** Since 1998 Health Canada has embarked on a series of stakeholder consultations, reviewed the contents of four separate Acts, and examined the existing gaps within the current legislation. In June 2003, Health Canada consulted the public on a proposal for new legislation, with various documents facilitating the public debate. The results of these consultations are available on its Web site ([renewal.hc-sc.gc.ca](http://renewal.hc-sc.gc.ca)). Extensive consultations with stakeholders were also undertaken to seek views on the proposal developed out of initial consultations.

### Strengthening compliance and enforcement

The Health Products and Food Branch's compliance and enforcement function needs to be reevaluated to ensure that it adapts to a changing world of risk and that it identifies the drivers of compliant and non-compliant behaviour. To that end, the Branch is developing a compliance and enforcement strategy to achieve the most effective and efficient compliance outcomes.

There are several key steps planned for the strategy:

- an assessment characterizing how risk has evolved in the regulation of the health product sector;
- an environmental scan of regulated parties, and an analysis of what influences their behaviour;
- development of performance indicators for measuring the effectiveness of compliance and enforcement activities;
- expanding the spectrum of modern compliance instruments, including new legislative and regulatory authorities;
- development of the strategy to include the ideal mix of instruments used, an implementation plan, and the assessment of resource requirements; and
- the launch of the strategy, with performance monitoring in place.

The authorities provided under the *Food and Drugs Act* do not address our current regulatory environment, and the Act does not address the Branch's expanded mandate. Furthermore, the current compliance instruments are reactive and focus on punishing non compliance. The compliance and enforcement strategy will address the shortcomings of these authorities with modern approaches and tools, with a goal to promoting compliant behaviour and deterring non-compliant behaviour.

The strategy will include several foundational projects, such as the development of a strategy to address counterfeit health products; development of a strategy to increase our effectiveness and oversight of health products coming into Canada; and efforts to increase international harmonization and regulatory collaboration. Finally, work to revise the external charging framework will be a key initiative in modernizing our legislative and regulatory frameworks.



### External Charging Initiative

One of the key components of a high-performing regulatory system is sustainable and predictable funding. To support this, the Health Products and Food Branch's External Charging Initiative is developing an up-to-date external charging framework that covers the regulation, licencing and post-market surveillance of health products.

The Branch originally introduced fees in 1994-95, which represent about 20% of overall Branch funding and 32% of the total cost of delivering the regulatory program for therapeutic products—including human and veterinary drugs and medical devices (activities in the natural health products area are not currently covered by user fees). 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 increasing costs of the regulatory system. One major international 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 will have new fees in place in 2006.

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 common policy framework that provides coherence across product and business lines within the Branch. The framework consists of a 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.

**Consultations.** The External Charging Initiative has a significant public involvement component, with a commitment to transparency, openness and fairness in all activities. Planned activities will inform and educate stakeholders, build awareness and support, and allow for dialogue to identify issues and concerns. On June 22, 2005, the first stakeholder consultation was held - over 40 participants provided feedback on the Branch's proposed approach to meet the requirements of the Act.

The Branch will finalize the policy approach in 2006-07, which will provide a framework in which fee proposals for individual product lines will be considered by stakeholders. Consultations on all therapeutic products are planned for 2006-07 and will be concurrent with the Branch's renewal efforts.

## Improving health outcomes by enabling access to new products

Canadians want timely access to breakthrough drugs and other health products that address unmet health needs. The Health Products and Food Branch is proposing a number of activities to foster innovation and improved health outcomes for Canadians:

- maintain and improve internationally-benchmarked regulatory performance metrics (e.g., review time, backlog reduction, number of submissions reviewed within time targets);
- strengthen bilateral relationships and international standard setting and harmonization;
- strengthen regulatory guidance for clinical research and product submissions;
- improve our scientific expertise, foster collaborations and develop a regulatory foresight capacity for high-quality regulatory advice to industry throughout the entire product life-cycle; and
- develop new regulatory frameworks for vaccines, radiopharmaceuticals and emerging technologies, such as nanotechnology, and for product-specific health claims for foods.

### Providing scientific advice

The proliferation of new technologies requires that regulators be mindful of not unduly impeding innovation and public access to new therapies while fulfilling their primary role of safeguarding public health and safety. The principle of providing scientific advice early on to industry, including small and medium size enterprises (SMEs), could help those industries be better prepared to meet the requirements for regulatory review. Discussions between the sponsor and the regulator on the science of new treatments and mechanisms for generating relevant information at early stages of the product life-cycle could contribute towards efficiencies in product development and review processes, fostering innovative technologies and therapies and facilitate earlier access to health products.

Scientific advice could be provided on any aspect of research and development relating to the quality, safety, efficacy and therapeutic effectiveness of health products. Such an approach would further help address challenges in the drug development process. In particular, it could:

- provide better safety data on new and innovative drug products by increasing the effectiveness of processes for generating, collecting, disseminating, and utilizing safety data;
- provide scientific advice to encourage early consideration of post-authorisation, pharmacovigilance and risk management/risk minimisation aspects and to improve the quality of product submissions; and
- help generate greater health benefits from investments in drug research and development by increasing the number and quality - in terms of addressing unmet health needs - of new products completing the drug development process.

## Policy on Public Input into the Review of Health Products

The Policy on Public Input into the Review of Health Products promotes the consideration of public input in Health Canada's evidence-based review of the safety and effectiveness of a health product, and describes when and how to seek input. It outlines a consistent, coherent, and predictable process for Health Canada and its stakeholders in keeping with our regulatory mandate and is grounded in the principles of accountability, fairness, openness, and transparency. It supports Health Canada's commitment to serve the public interest through quality decision making.

While respecting its regulatory mandate and responsibilities, Health Canada will be **accountable, open, and transparent** in the decisions it makes in the review of a health product. Drawing from Government of Canada policies and commitments, including the Health Products and Food Branch's *Public Involvement Framework*, the development of the policy has been guided by the following commitments:

**Independence and accountability in our decision making.** Health Canada makes decisions on a health product objectively, independently, and without bias in keeping with its legislated mandate under the *Food and Drugs Act* and regulations. For all of its decisions, Health Canada will show how scientific information and public input was used.

**Making decisions in the public interest.** Health Canada's mission is "to help the people of Canada maintain and improve their health." Parliament has determined that regulatory decisions in the public interest require Health Canada to identify and assess safety and effectiveness issues to determine the level of acceptable risk of a health product when weighed against its benefits. Health Canada recognizes that public input can be helpful in this decision-making process.

**Openness and inclusiveness in our review process.** Health Canada recognizes that public input from a variety of sources leads to more informed analysis of the safety and effectiveness of a health product.

**Transparency.** Respecting the requirement to protect the privacy rights of individuals and confidential commercial information, Health Canada will provide the public with sufficient information on the review of a health product and on issues under consideration to support informed input.

**Timeliness.** Health Canada will inform the public of opportunities to provide input early in the review process and always endeavour to give the public sufficient time to prepare.

**A flexible approach.** Health Canada will use a variety of approaches to gather public input when it is sought in the review of a health product, depending on the issue under consideration and the nature of the input required. For example, we might use face-to-face and written consultations, workshops, dialogues, advisory body meetings, and public forums.

The outcomes of having a policy that describes when and how to involve the public in the review of health products will be: more open and transparent regulatory processes and decisions, more consistent and predictable processes, and enhanced decision-making within a risk-management framework.

**Consultations:** Public consultations on the draft policy were launched in July 2006 on the Health Canada website. Results will be available at [www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/public-rev-exam/index\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/public-rev-exam/index_e.html)

## International regulatory cooperation

The Health Products and Food Branch will cooperate with other international regulators to maximize existing resources and adopt best practices. Approaching standard setting and regulatory decision making from a global perspective will provide the Branch with regulatory consistency, improved regulatory performance, harmonization (where appropriate and desirable), and enhanced information sharing through mechanisms such as work sharing.

The three key objectives of the Branch's engagement in international regulatory cooperation are the following:

### **Develop and strengthen international relations with key regulatory counterparts and other organizations**

By strengthening its bilateral relationships, activities, and regional cooperation with key partners, the Branch will improve its regulatory system performance. Strengthened relationships will facilitate the adoption of best practices, the timely exchange and integration of scientific knowledge, improved transparency and ultimately the ability to make better regulatory decisions. This translates into activities such as developing concurrent and harmonized submissions with other regulators, increasing the use of foreign reviews in decision making and developing work-sharing mechanisms. Developing a Branch-led global work-sharing network would allow the Branch to work with regional representatives to reduce duplication of regulatory activities, build confidence in Canadian data assessment, and seek new opportunities to transform global regulatory efficiency and effectiveness.

### **Active and transparent collaboration in international standards setting, equivalency and harmonization initiatives**

To ensure that the Branch's multilateral efforts bring the most benefits to Canadians, a strategic approach to standard setting and harmonization will involve reviewing existing regulations against international standards; harmonizing and adopting new regulations and policies, where beneficial and appropriate; implementing adopted standards and regulations; and strengthening the Branch's role as a leader in certain standard-setting bodies, for example the International Conference on Harmonization, and the CODEX Alimentarius Commission.

### **Strategic engagement with countries that have developing regulatory systems**

Strategic engagement with countries with developing regulatory systems will facilitate a two-way sharing of knowledge and practices and will mitigate the risks to Canadians from health products, food and disease originating from these countries. It will provide coordinated assistance to these countries by collaborating with international partners and multilateral organizations.

## Review of the *Natural Health Products Regulations*

The *Natural Health Products Regulations* (NHP Regulations) came into force on January 1, 2004 following extensive consultations with stakeholders. The intent of the regulations was to provide an appropriate level of regulatory oversight for relatively low-risk products, while providing consumers access to natural health products that are safe, effective and of high quality.

However, challenges have been identified with the implementation of this regulatory framework. In some cases, the letter of the law does not reflect the original intent of the drafters. For example, the framework is intended to cover only products that are appropriate for self-care, something which is not explicitly outlined in the NHP Regulations. Furthermore, the lack of sufficient transition provisions when the NHP Regulations came into force created a serious review backlog that has slowed the issuance of product licences.

### Review of the regulatory framework for natural health products

To address these challenges, Health Canada will review its *Natural Health Products Regulations*. The review will provide stakeholders with a sustainable and appropriate regulatory framework for natural health products. Furthermore, this process is consistent with the eight policy objectives of the Blueprint for Renewal. In particular, the review will focus on applying regulatory interventions proportional to risk, moving to a system that makes the best use of all types of evidence, and moving to a proactive and enabling regulatory system.

This approach will provide sustainability and improve efficiency by addressing gaps in the Regulations and ensure that the policy objectives for safe, effective and high-quality products continue to be met.

We estimate that the review of the Regulations will take three years and be implemented in three phases:

**Phase I: Non-regulatory options.** This phase was initiated in late 2005 with the review of existing natural health product guidance documents and policies. It is intended to ensure that all guidance documents and policies accurately reflect regulatory requirements and provide guidance that reflects the relative low risk of the products. Furthermore, the review was undertaken in an open and transparent manner with direct input and recommendations from stakeholders.

**Phase II: Regulatory amendments for specific items.** This phase will focus on developing regulatory amendments to address issues identified by Health Canada and stakeholders since the implementation of the Regulations. Amendments could be prescribed to limit the scope of the Regulations. For example, the NHP definition could be modified to exclude certain low and high risk products.

**Phase III: Focussed review of framework and Regulations.** This phase will look at the Regulations from a macro perspective - structure of the Regulations, main components and fundamental elements. We will review the Regulations and solicit stakeholder views to identify what parts of the framework need to be changed and updated. Based on the outcome of this review, we may propose additional amendments.

### Meeting the needs of stakeholders into the future

Health Canada is confident that reviewing the *Natural Health Products Regulations* will contribute to a regulatory framework that is flexible, effective, efficient and sustainable for regulating NHPs in the 21<sup>st</sup> century.

## The Veterinary Drugs Program

Health Canada is responsible for protecting human and animal health and the safety of Canada's food supply. Through the Veterinary Drugs Directorate (VDD), Health Canada evaluates and monitors the safety, quality and effectiveness of veterinary drugs, sets standards and promotes the prudent use of veterinary drugs administered to food-producing and companion animals. It ensures the safety of foods from animals treated with veterinary drugs, and that veterinary drugs sold in Canada are safe and effective for their intended purpose and pose no threat to humans in the form of harmful residues from animal products such as meat, milk, eggs, fish and honey.

The Directorate is facing a number of issues, including:

- Stakeholder requests for improved drug submission review performance, and improved measurement and reporting;
- Establishing and listing Maximum Residue Limits (MRLs) for veterinary drugs in foods;
- Labeling for Antimicrobial Resistance (AMR) and food safety;
- Pharmacovigilance program to inform decision making;
- Lack of regulatory framework for Veterinary Natural Health Products;
- International harmonization with international bodies, including CODEX and VICH, to minimize the impact of regulatory differences, encourage submissions and lead to better availability of veterinary drugs; and
- Address the lack of approved drugs for minor uses and minor species (MUMS).

In 2006-07, the Directorate plans to deliver on its mandate through a range of activities:

- Improving the management of drug submissions by introducing new initiatives and efficiencies in the drug review process - including electronic review of submissions, external charging, and updated policies and procedures;
- Making its activities transparent and open by putting in place appropriate initiatives to deal with the public, stakeholders and public servants;
- Working closely with our international scientific partners - U.S. Food and Drug Administration Center for Veterinary Medicine, Australian Pesticides and Veterinary Drugs Authority and national partners - on issues of food safety, for example harmonization, Minor Uses Minor Species, Antimicrobial Resistance, and Emergency Drug Release Program;
- Developing a regulatory framework for Veterinary Natural Health Products; and
- Managing key issues, for example the use of veterinary drugs in aquaculture, honey, etc.

## Regulatory Modernization Strategy for Food and Nutrition

Health Canada is developing a Regulatory Modernization Strategy for Food and Nutrition. This strategy will position Health Canada to be recognized, nationally and internationally, as a food safety and nutrition authority that has open, transparent, and measurable regulatory processes to address food hazards and the nutritional value of food. The Strategy will enable the Food Directorate, as Health Canada's primary regulatory authority for food safety and nutrition, to develop and maintain a food regulatory system that is flexible, risk-based, and provides timely responses to current and emerging food safety and nutrition issues.

The Strategy will:

- facilitate the management of a more dynamic food regulatory system that can anticipate emerging food issues and pro-actively respond;
- promote a science- and risk-based approach to regulating food-related risks to health;
- facilitate appropriate collaboration and cooperation with partners - governmental food portfolio partners, regulatees, and citizens;
- help to maximize the contribution of the food supply to a healthy population; and
- promote a food continuum perspective on food safety, where differing and respective health protection roles are integrated and mutually re-enforced.

This Strategy will provide the strategic basis for new regulatory and policy frameworks for food safety and nutrition, and will in its early stages support early action on established food regulatory priorities. Notably, it will include:

- a new regulatory framework for expanded health claims for foods to permit health claims that support informed consumer choice and that are truthful, substantiated and not likely to lead to harm to consumers; and
- examination of, and improvements to, pre-market regulatory processes for food additives and novel foods to ensure that the food regulatory system manages its resources and expertise in such a way that places maximum time and resource investment in higher-risk food safety and nutrition issues.

**Consultations.** Health Canada will invite continued and meaningful involvement of stakeholders to provide increased clarity of respective health protection roles throughout the food continuum.

### 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 the developments in biotechnology. The regulations governing vaccines are a mix of general regulations - applicable to all biologics, including vaccines - and vaccine-specific regulations. No new vaccine-specific regulations have been introduced to the *Food and Drugs Act* and regulations for vaccines discovered after 1963. However, since 1963, existing regulations have been updated or amended to keep up with scientific advancements and changes in nomenclature. Some sections were amended from specific requirements to general requirements to allow for 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.

The existing regulatory framework for radiopharmaceuticals also needs to be reviewed and updated. The current regulations may not be 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 associated risks. Also, there is little in the way of specific guidances and policies for stakeholders.

Therefore, a systematic review of radiopharmaceutical regulations is necessary. This review will promote a life cycle approach to regulating by assessing regulations against good governance criteria in accordance with government regulatory policies.

The outcome on the reviews for vaccines and radiopharmaceuticals will result in new regulations that:

- advance the public interest and instill trust and confidence at home and abroad;
- make decisions based on evidence and the best available knowledge and science in Canada and worldwide;
- create more accessible, understandable and responsive regulations through greater inclusiveness, transparency, and public scrutiny;
- promote effectiveness by ascertaining that over time the benefits of regulation justify costs, by focussing human and financial resources where they can do the most good and by demonstrating tangible results to Canadians; and
- promote timeliness and efficiency through cooperation and coordination across the federal government, with other governments in Canada and abroad, and with businesses and Canadians.



## Glossary

These plain language definitions are intended for general understanding, and are not necessarily the formal definitions used by Health Canada or those that appear in legislation or regulations.

**Adverse reaction:** Any undesirable effect of a health product. This can range from a minor effect such as a skin rash to a life-threatening one such as liver damage.

**Biologics:** A subset of therapeutic products that are made from biological starting material, including those obtained by recombinant DNA procedures. They include vaccines, blood and blood products, and many hormonal products such as insulin.

**Clinical trial:** A scientific study, using a test population, designed to test the safety, efficacy and quality of drugs or medical devices on human subjects.

**Common Drug Review (CDR):** A single common process for reviewing new drugs to assess potential coverage under Canadian public drug benefit plans, established in September 2001 by federal, provincial and territorial health ministers.

**Drug:** Any substance used in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, and in restoring, correcting or modifying organic functions in humans or animals.

**Drug review process:** Drugs are only approved for sale in Canada once they have gone through the drug review process. Drug applications are carefully reviewed by scientists in the Health Products and Food Branch of Health Canada. These scientists assess the safety, efficacy and quality of a drug. If the benefits of the drug outweigh the risks, the product is given authorization to be marketed in Canada.

**Effectiveness:** Whether a drug achieves its desired effect in the real world.

**Efficacy:** Whether a drug has the ability to bring out the intended beneficial effects in a controlled environment, for example, with no interactions with other drugs or diseases.

**Guidance documents:** Manuals, policy interpretations, guidelines and other texts that support a better understanding of regulations and how to participate in the regulatory process.

**Health Products and Food Branch (HPFB):** A science-based organization within Health Canada that regulates products, including pharmaceuticals, radiopharmaceuticals, biologics and genetic therapies, medical devices, natural health products, veterinary drugs and food, as required by the Food and Drugs Act and Regulations.

**Inspection:** An independent evaluation, conducted by an objective, unbiased inspector or inspection team, to assess an establishment's compliance with set standards or regulations. Inspections are normally conducted on a multi-year cycle or as required.

**International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use) (ICH):** A global project dedicated to reducing duplicate testing of new medicines, to make better use of resources, safeguard public health and avoid unnecessary delays in making new medicines available.

**Labelling:** Includes any legend, word or mark attached to, included in, belonging to or accompanying any therapeutic product and is commonly understood to mean all packaging and product inserts, including the drug product monograph.

**Medical device:** Any article or instrument used in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, and in restoring, correcting or modifying organic functions in humans or animals. Devices also include those used in the prevention, diagnosis and care of pregnancy and do not include a drug.

**Natural health products:** Include vitamins, minerals, traditional medicines, medicines made from plants, bacteria and fungi, probiotics, amino acids and essential fatty acids (such as Omega-3). Also refer to definition of drug.

**New Drug Submission (NDS):** The formal process of applying for market approval of a new drug product. A new drug is any drug that has not been sold in Canada for sufficient time and in sufficient quantity to establish its safety and effectiveness under use or its recommended conditions for use.

**Pharmaceuticals:** Mostly synthetic products that are made from chemicals, pharmaceuticals include prescription and non-prescription drugs, disinfectants, and low-risk products such as sunscreens, antiperspirants and toothpaste.

**Post-market surveillance:** The process of tracking drugs and other therapeutic products, already approved and on the market, to assess signals and safety trends once these products are in use among a wider population.

**Product monograph:** A factual, scientific document, devoid of promotional material, that describes the properties, claims, indications and conditions of use for a drug and that contains any other information that may be required for optimal, safe and effective use of the drug. Product monographs are submitted to HPFB as part of a new drug submission.

**Quality:** An accepted standard of production methods and manufacturing facilities, including the premises, equipment, in-process controls and tests during fabrication, packaging and labelling, to ensure consistent results in final products that are safe, efficacious, pure and stable.

**Radiopharmaceuticals:** A pharmaceutical, biological or drug that contains a radioactive entity. Radiopharmaceuticals are primarily used for various imaging functions but can also be used in a therapeutic capacity.

**Risk:** Chance of harm: a health hazard. All therapeutic products that offer benefits are accompanied by risks. Although risks can be controlled and managed, they cannot be fully eliminated. Risk varies by product and changes through the product life cycle. The definition of risk within the context of safety,

quality and efficacy of therapeutic products continues to develop globally and through international harmonization initiatives.

**Risk communication:** The exchange of information about health risks between experts, other interested parties and the public.

**Safety:** The relative risk of harm. Safety is aimed at defining the type, level and scope of adverse events, reactions and hazards to be balanced against the benefits of a health product so that an appropriate risk-benefit assessment can be developed and an appropriate therapeutic index for a health product can be established.

**Stakeholder:** An individual, group or organization that is affected by or interested in an issue or policy. Stakeholders, interested parties and affected parties are segments of the public. Stakeholders may include health professionals, academia, industry and patients.

**Summary Basis of Decision (SBD):** A public document that outlines in technical language the risk-benefit analysis and scientific considerations that have factored into HPFB's decision to grant market authorization for a drug or medical device. The document provides regulatory, quality (chemistry and manufacturing), efficacy and safety information.

**Therapeutic products:** A broad range of products, including drugs (pharmaceuticals, radiopharmaceuticals, biologics and genetic therapies), natural health products and medical devices.