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Health Products and Food Branch



## **Blueprint for Renewal Report: Regional Consultation Sessions**

November 2006

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## Background

In October 2006, the Health Products and Food Branch (HPFB) released the discussion document *Blueprint for Renewal: Transforming Canada's Approach to Regulating Health Products and Food* to communicate our current thinking with respect to the modernization of the health products and food regulatory system.

The discussion document articulates the case for renewal, as well as the vision and objectives of our plan. A snapshot of the plan is presented in Annex 1. The full discussion document is available on the Health Canada Web site at [www.healthcanada.gc.ca/hpfb-blueprint](http://www.healthcanada.gc.ca/hpfb-blueprint).

In October 2006, HPFB launched a series of consultations related to the Blueprint to seek the views of our stakeholders. Seven regional consultation sessions were held with stakeholders over the month of November 2006. These sessions took place in Toronto, Halifax, Winnipeg, Longueuil, Ottawa, Vancouver and Edmonton (see Annex 2 for a list of participants for each session). At the same time, an electronic consultation on the Blueprint took place from October 26 to December 6, 2006.

In addition, HPFB conducted a series of consultations on specific Blueprint initiatives over the second half of 2006—registration and disclosure of clinical trial information, review of the clinical trials regulatory framework, a policy on public input into the review of health products, and a proposed progressive licensing framework for pharmaceuticals and biologics. Additional consultations are planned for 2007, including external charging; the review of the Natural Health Products regulations; a regulatory modernization strategy for food; and a proposed regulatory framework for food-related health claims. We invite you to consult our Web site for more details.

The input we receive from these various consultations will help inform the further development and implementation of the Blueprint plan and its various components.

This report presents detailed findings and observations we heard during these regional consultation sessions. A summary report of the regional sessions as well as a report of the electronic consultation are also available on the Blueprint's Web site.

## Key messages we heard from participants in the regional consultation sessions

### *We heard...*

#### **Strong support for**

- adopting product life-cycle approaches
- strengthening post-market surveillance and risk communication
- addressing product categorization issues
- international regulatory cooperation – advancing harmonization and work-sharing with other regulators
- continuing progress on enhancing transparency, openness and accountability
- better synchronization of research and development, regulatory and health system objectives
- implementing change initiatives as they are ready

#### **Key comments and suggestions**

- Protecting the health and safety of Canadians should continue to be at the core of our renewal efforts
- Consumer information and education must be a priority and a clear focus in the Blueprint
- The Branch's authorities and capacity for compliance and enforcement of existing regulations must be strengthened
- Legislative agenda in support of Blueprint objectives should be fast-tracked
- The review of the Natural Health Products regulations should focus on correcting implementation irritants and ensuring adequate resources are in place to deliver the program
- Health Canada should enhance its efforts to support the development of innovative products that address unmet health needs
- Adequate resources will be required in order to successfully deliver on the objectives set out in the Blueprint, and to report on progress in realizing them

#### **Areas requiring further discussion**

- How is the precautionary principle applied in a risk management framework?
- What is the appropriate role for health professionals, industry, provincial governments, and other stakeholders in delivering on the objectives set out in the Blueprint?
- To what extent, and how, can decision making across the access continuum (i.e., licensing, pricing, formulary listing) be better aligned?
- How can all players work together to improve reporting around adverse drug reactions?
- How can all players in the regulatory system do their part to ensure that information on the risks and benefits of health products and food is communicated effectively to the appropriate people in a timely fashion?
- Further discussion on the renewal of the external charging regime will be required with stakeholders.
- Given the primary focus on drugs and other therapeutic products in the Blueprint, further discussion around food is required.

## Summary of the regional consultation sessions

### Introduction

Seven regional consultation sessions with key stakeholder groups took place in November 2006 to seek stakeholders' views on the Health Products and Food Branch (HPFB) Blueprint for Renewal initiative. The sessions were held in Toronto, Halifax, Winnipeg, Longueuil, Ottawa, Vancouver and Edmonton.

The participants at the sessions represented a broad range of key Branch stakeholders, including industry representatives, health care professionals, academics, and patient and consumer groups (provinces and territories are being consulted separately).

The sessions were chaired by HPFB's Assistant Deputy Minister, Mr. Neil Yeates, and facilitated by Health Canada personnel. Each session began with an overview presentation of the Blueprint by Mr. Yeates. Participants then had an opportunity to seek clarifications on the presentation and to provide their organization's views and perspectives (the Blueprint discussion document and the overview presentation are available on the Blueprint web site at [www.healthcanada.gc.ca/hpfb-blueprint](http://www.healthcanada.gc.ca/hpfb-blueprint)). The session then closed with a facilitated discussion between participants and Health Canada representatives.

The following summarizes the main observations, suggestions and discussion points.

### General comments and perspectives

Generally, participants at the sessions agreed with the diagnostic and the case for renewal presented in the Blueprint, as well as with its broad vision and objectives. In addition, many indicated that they are ready to do their part to contribute to the success of the initiative.

Some, although supportive of the overall direction, reserve final judgment until they see the implementation details and roll-out of specific Blueprint initiatives.

Many participants noted that the fundamental role of Health Canada in protecting the health and safety of Canadians is not adequately reflected in the Blueprint. It was suggested that this role should be clarified and articulated, possibly in a new section on values and principles. Some suggested a small workshop could be a useful way of developing a comprehensive set of values and principles that should underpin Blueprint initiatives.

Strong support has been expressed for many of the orientations outlined in the Blueprint, such as:

- adopting life-cycle approaches in the regulation of therapeutic products, as opposed to the current point-in-time approach;
- strengthening post-market surveillance and risk communication;
- addressing product categorization issues and irritants – for example, some low risk products that are regulated under the Natural Health Product regulations;

- continued progress to enhance the transparency and openness of our activities, as well as our accountability to Canadians; and
- better synchronization of research and development, regulatory and health system objectives.

Mixed views have been expressed on other topics, such as on the concept of regulatory interventions proportional to risk, as well as on the precautionary principle versus risk management of health products. Some participants felt that the latter two concepts are incompatible and that a move toward more risk-based regulatory interventions for health products would indicate a diminished focus on protecting the safety of Canadians.

A number of gaps in the Blueprint were identified by participants. Two gaps in particular were mentioned in all the consultation sessions:

- much more needs to be done in the area of compliance and enforcement, both at the authorities and capacity levels
- there was a strong message that the Blueprint should include a greater focus on consumer information and the role that Health Canada could play in this area.

Participants also felt that in order for the Blueprint implementation to be successful, it will be critical for the Health Products and Food Branch to secure adequate and sustainable resources (including a renewed cost recovery regime), as well as new legislative tools.

Some participants expressed concerns that the Blueprint is very ambitious and will require setting priorities. The inclusion of an implementation plan with timelines in relation to the various initiatives was recommended.

## **Specific comments on various themes**

### **Roles and responsibilities**

Many participants felt that the roles and responsibilities of the various players throughout the regulatory process should be better aligned to improve timely access to safe and effective health products.

Health Canada was encouraged to play a role in working with and informing certain sectors about how they can contribute to an effective regulatory system – for example, physicians want to better understand the expectation for reporting of adverse events as part of the post-market surveillance system.

Many participants encouraged better coordination between Health Canada and the provinces and territories in general, and with the Common Drug Review (CDR) in particular. Participants expressed concern that products approved by Health Canada (guided by considerations of safety, quality and efficacy) are essentially inaccessible when they are not recommended for reimbursement on public drug plans by the CDR (guided by considerations of therapeutic and cost-effectiveness). This is an area of particular concern for drugs targeted at rare disorders and unmet health needs.

It was expressed that an effective and modern regulatory regime will require active stakeholder participation in decision-making processes. It was noted that Health Canada should more systematically seek input from stakeholders on regulatory activities that have a direct impact on them and that resources should be made available for smaller organizations that have limited capacity to participate in stakeholder engagement activities.

### **Post-market surveillance and risk communication**

A strong post-market surveillance system was considered essential by most participants, especially in the context of a progressive licensing framework. The difference between, and the need for both, proactive and reactive surveillance was highlighted.

One common area of discussion and concern was the under-reporting of adverse drug reactions (ADR). Some participants continued to advocate for mandatory reporting by health professionals while others indicated that implementing strategies to address under-reporting would be more efficient and effective. Improved ADR reporting is an area that will need to be strengthened in the post-market surveillance regime.

Interest was expressed around an electronic adverse drug reaction reporting system and around the implementation of mandatory registration and disclosure of Phase IV clinical trial information by industry, as a way of generating improved data on safety and effectiveness in a “real world” setting. There was also support for the creation of a network of national centres of excellence as part of the National Pharmaceuticals Strategy to improve the collection, analysis and dissemination of information on post-market safety and effectiveness.

Some participants recommended the development of better tools to communicate risk to the public. It was also suggested that Health Canada’s post-market surveillance program could consider tracking health products in order to more easily contact affected patients when a problem arises.

### **Compliance and enforcement**

Many participants mentioned that the Blueprint did not adequately address current gaps in Health Canada’s capacity and authorities around the compliance and enforcement of the current health products regulatory frameworks. It was suggested that strengthened compliance and enforcement be a distinct objective in the Blueprint. Securing new legislative authorities in this area was deemed critical for the successful implementation of the Blueprint.

### **Openness and transparency**

Openness and transparency were identified by many participants as values that should underlie the entire regulatory process, although many recognized the challenges in doing so effectively. Information on both products and product reviews should be readily available, as should information on the regulatory system itself. At the same time, transparency and openness should be values that are well integrated into all public involvement activities, such as advisory committees, with accountability mechanisms in place

to ensure that these principles are respected. Integrating this kind of openness throughout the regulatory process will help all Canadians, from health care providers to consumers, to better understand how to access health product and food-related information, as well as how to become involved in the decision-making process when appropriate.

### **Consumer/provider information and education**

Participants in all the regional sessions noted the importance of communicating effectively with consumers, including vulnerable populations. Messages to the public, particularly those around the risks and benefits of health products and food, must be clear, and communicated in consistent and simple language so that people can make informed choices about their health. There were calls for better information to:

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

It was noted that the use of the Internet is insufficient to communicate effectively with all consumers. Participants identified the need for unbiased and objective information as well as direction around how to judge the reliability of information. It was also suggested that consumer information should be readily available and communicated in French as well as in English. Health Canada was seen as having a strong mandate to provide authoritative information to consumers and health providers. Participants suggested that Health Canada (including the regional offices) should work more closely with consumer groups, health care providers, and others in the regions to ensure information is effectively communicated.

### **Special Access Program, Clinical trials, orphan drugs**

Participants welcomed the review of the Special Access Program and for the 2001 clinical trials regulatory framework as opportunities to ensure the appropriate use of these key access mechanisms to drugs not yet licensed in Canada.

It was noted that there have been many positive changes since the new regulatory framework for clinical trials was put in place in 2001 (e.g. improved timeliness of approvals of clinical trial applications) but that the regulations would need to adapt to reflect changes in the clinical trials environment (e.g., move toward adaptive clinical trials).

There were calls for information from clinical trials to be fully disclosed. Some participants hoped that under new legislation, confidential commercial information protections would no longer restrict safety

and efficacy data from being available to the public. Some also recommended exploring how the extrapolation of clinical trials results to different populations might be put in place.

Some participants recommended that Health Canada establish an orphan drugs policy, which would put in place incentives for sponsors to develop treatments to address rare disorders and unmet health needs.

### **International regulatory cooperation**

Participants expressed support for exploring options to establish work sharing agreements with other regulators to improve the efficiency and effectiveness of HPFB's regulatory activities. However, it was noted that Canada should retain final regulatory decision-making authority.

International harmonization, collaboration and partnerships are seen as important to strengthen Canada's regulatory regime, enhance competitiveness and facilitate better decisions. Better collaboration would also allow for greater efficiencies and help reduce overlap and duplication of efforts.

Compliance and enforcement and post-market surveillance were mentioned as key areas to further international collaboration, to pool scientific resources, and to harmonize standards where appropriate.

### **Product categorization, review of the Natural Health Products regulations**

There were many calls among meeting participants for clarity related to product categorization, particularly around the categorization of "grey zone" products that do not fit clearly into existing categories of natural health products, food, drugs and/or cosmetics. The lack of clarity was seen as detrimental to both industry and consumers.

Participants supported the review of the Natural Health Products regulations, emphasizing that this review should not "undo" the good work that has already been done. Participants are looking forward to providing input on the categorization of "grey zone" products, clarifications of industry guidelines, and implementing a risk-based regulatory scheme similar to that currently in place for medical devices.

### **Observations on product lines other than human drugs**

Many participants made the observation that the Blueprint is heavily focused on human drugs and that little detail has been provided on how the various Blueprint initiatives will apply to other product lines regulated by the Branch, such as medical devices, veterinary drugs and food.

Interest was expressed in how the Blueprint would apply to food and nutrition. Health Canada staff noted that a separate consultation document on the food regulatory modernization strategy would be available in early 2007.

Some participants were particularly interested in how Health Canada could promote better information to consumers at the point of purchase, and regulatory requirements related to novel foods. There was support to continue with the development of a framework for food-related health claims. It was also suggested that Health Canada and the Canadian Food Inspection Agency need to better define their roles

and responsibilities and communicate them to the public in an effort to reinforce public trust in the food system.

### **Conclusion and next steps**

HPFB's regional consultation sessions on the Blueprint for Renewal served to demonstrate that there is strong support for regulatory system renewal priorities articulated in the Blueprint. Many important suggestions for improvement were offered, and will be incorporated in a second version of the Blueprint – planned for release in April 2007 with the release of the Health Products and Food Branch's new Strategic Plan.

The electronic consultation report will be posted on the Web site in Spring 2007, as well as regular progress reports on the development and implementation of the Blueprint ([www.healthcanada.gc.ca/hpfb-blueprint](http://www.healthcanada.gc.ca/hpfb-blueprint)).

## Regional Reports

### Regional Report - Toronto, Ontario

November 3, 2006

#### Questions and answers

Questions from Toronto participants covered a wide range of Blueprint topics. Some focused on the status of various reviews of regulatory programs, including the Special Access Program. Participants were told that more information will be provided in the New Year on when specific elements of the Blueprint will be pursued and how. Others asked about the links between the Blueprint and other initiatives such as Smart Regulation and Legislative Renewal, and were assured that these initiatives have informed current thinking and that legislative modernization continues to be a priority for the Branch. Some participants noted that the Blueprint seemed primarily focused on pharmaceuticals, and asked whether and how, for example, food issues would be included. They were assured that the Branch sees the focus on food as different, and that this will be reflected in HPFB's Food Modernization Strategy. In response to questions, Branch representatives also noted the following:

- The Branch's move to the use of the term "evidence-based" instead of "science-based" is based on an increased emphasis in the Branch's decision-making processes on including evidence beyond science per se to include real-world experience and experiential knowledge.
- The Branch's is working toward increased international collaboration. The goal is to ensure that Canada's standards and definitions are sufficiently aligned to permit collaboration with, for example, the United States Food and Drug Administration (US FDA), while maintaining Canada's high standards of safety;
- The Branch's Policy on Public Input, which was the subject of recent consultations, is an important tool in establishing consistent principles and guidance for openness and transparency in HPFB's regulatory reviews;
- HPFB has increased public access to information about adverse drug reactions (ADR) through the creation of the MedEffect website. The Branch is also working to improve public awareness about ADRs, including developing guidance for consumers to report adverse drug events.

Branch personnel also indicated those Blueprint activities that have been identified for short term attention. They include:

- Consultation on the natural health products regulations
- Modernizing food regulations, including health claims and food fortification
- Clinical Trial Regulations Review
- Policy on Public Input into the Review of Health Products

- **Progressive Licensing Framework**

Branch personnel also indicated that resources to support the broad array of Blueprint initiatives will be considered as part of a review of HPFB's programs and resources currently underway, through the Branch's Strategic Plan exercise (business and operational) beyond 2007, and through updating HPFB's cost-recovery regime.

## **Prepared interventions by participants – Key themes**

Several key issues were raised by Toronto participants, based on their assessment of the Blueprint for Renewal. These included:

### **Consumer information and education**

The importance of consumer information and education was frequently raised, with many feeling that it should be featured more prominently in the Blueprint. Participants underscored Health Canada's responsibilities toward the public to provide authoritative consumer information. Some also felt that Health Canada needs to do a better job of communicating its regulatory role to the public and internationally, which would increase public confidence in the department. It was recommended that the direction of the Blueprint should be much more consumer and stakeholder-centered, as should all of Health Canada's future prioritizing.

### **Food regulations**

Many participants felt that improvements to the food regulatory system were under-emphasized in the Blueprint for Renewal. Further, a participant commented that many of the elements introduced in the Blueprint, such as post-market surveillance, were not applicable to the area of food. Health Canada was encouraged to outline explicitly which portions of the Blueprint related to food.

Many participants commented that Health Canada needs to better define its roles and responsibilities in relation to both Agriculture and Agri-food Canada as well as to the Canadian Food Inspection Agency (CFIA). In some areas, mainly research, responsibility appears to overlap. One participant felt that Canada should be more aligned with the United States Food and Drug Administration (US FDA).

Participants commented on novel and imported foods. Some felt that the approval process in Canada was too long for items which pose low risks, especially in the area of food additives. One participant felt that the process to approve imported foods is too slow, while another felt that it is too fast, jeopardizing the safety and quality of imported foods.

### **Interventions proportional to risk**

Some of the participants in Toronto expressed caution concerning the implementation of a regulatory approach based on interventions proportional to risk. They were concerned that problems with "low-risk" products may be overlooked under such a regime. Other participants preferred the use of the

“precautionary principle”, which they felt was better aligned with HPFB’s fundamental public protection mandate and offered needed balance to industry interest in early market access.

### **Strengthening evidence-based decisions**

Participants suggested that Health Canada should consider collaborating with a neutral science-based body to improve its access to evidence-based information and advice and strengthen its reputation as a science-based organization.

### **Adverse drug reaction reporting**

Participants supported increased access by the public and clinicians to a joint provincial/territorial/national Adverse Drug Reaction database as well as to all of the safety and efficacy data from clinical trials. Currently, much of this data is still considered confidential commercial information and as such is not available to the public.

## Regional Report - Halifax, Nova Scotia

November 6, 2006

### Questions and answers

Questions were posed by participants on several Blueprint topics, including:

- *how the Blueprint for Renewal's planned compliance and enforcement strategy may affect the role of provincial/territorial regulators*

Participants were assured that HPFB will continue to work collaboratively with regulators at the provincial/territorial level, and minimize duplication and overlap. Health Canada is also exploring more modern tools to encourage compliant behaviour and to discourage non-compliance, including a ticketing regime with more reasonable penalties.

- *how Health Canada intends to integrate consideration of real-world effectiveness in its reviews*  
Branch officials indicated that this is an issue that HPFB and the Provinces/Territories are actually considering in the context of the National Pharmaceutical Strategy (NPS) as well as in the development of Progressive Licensing Framework (PLF).

### Prepared interventions by participants – Key themes

Participants addressed a number of issues arising from the Blueprint, including the following:

#### Consumer information and education

Like those at the Toronto session, many participants noted that the Branch's renewal initiatives should more prominently feature a consumer-centric approach, and that it should be clearer how consumers can contribute throughout the regulatory process. It was suggested that the regional offices could and should play a larger role in this. As well, it was felt that Health Canada should better define the roles and responsibilities of pharmacists and other health professionals, as well as those of consumers, in order to determine what role each should play in developing and providing consumer information and education. Participants encouraged Health Canada to ensure that consumer education is appropriate to culture and language, particularly French, as well as to specific populations such as seniors.

#### Enforcement and compliance

For many participants, there was concern about how health products and food manufactured outside of Canada are labelled and monitored, and how regulations could or should be enforced in these areas. The ability to impose fines and accountability were cited as problems with the current system. Participants felt that tougher enforcement may be required to encourage greater compliance in some areas, and supported the establishment of accountability structures to achieve this.

### **Adverse drug reaction (ADR) reporting**

A number of participants were supportive of efforts made by Health Canada to strengthen ADR reporting, but felt that they need a better understanding of Health Canada's expectations, and how ADR reporting information will be used. It was suggested that Health Canada work more closely with medical and consumer groups to educate these communities on these issues.

### **Natural health products (NHPs)**

Participants supported and expressed interest in being involved in Health Canada's upcoming review of the NHP regulations, noting that it will be a good way of identifying some of the regulatory problems or gaps that exist in this regime. Health practitioners also noted that they are increasingly being asked questions related to NHPs, and require better access to accurate and reliable information.

### **Product lifecycle approach**

Participants expressed support for a product lifecycle approach that would result in greater stakeholder involvement throughout the regulatory process. Participants also felt that Health Canada should clarify where responsibility for the safety and safe use of products lies throughout the lifecycle, and that it should include consumers as well as manufacturers. It was noted that strengthened post-market surveillance may mean that demand for skilled evaluators could exceed supply, and that Health Canada should take steps now to address this in order to ensure that the quality of its science-based reviews is not jeopardized.

### **Food regulation**

Participants noted a high level of consumer's interest in food and nutrition, and felt that the Blueprint's focus on nutritional quality and safety in food regulation should be greater.

## Regional Report - Winnipeg, Manitoba

November 10, 2006

### Questions and answers

Questions from participants in Winnipeg included:

- *whether there has been any consideration on extending the grace period for compliance with the Natural Health Product regulations*  
The Branch indicated that, as part of the ongoing review of the NHP regulations, a number of possibilities are being considered to more efficiently review the 40,000 NHPs currently on the market.
- *what Health Canada will include in its approach to food health claims*  
Further details on the specific elements of health claims legislation will be decided after the forthcoming public consultations on health claims, where these issues will be discussed.
- *how Health Canada intends to provide objective consumer information to targeted or hard-to-reach audiences, including Francophones or those without web access*  
Branch officials indicated that HPFB is developing a consumer information strategy, and will consider these issues.

### Prepared interventions by participants – Key themes

#### Regulatory interventions proportional to risk

In adopting this approach, participants emphasized that the health and safety of Canadians should remain Health Canada's priority. Participants also noted that they would like greater clarity on how Health Canada will define "risk" in product areas, such as self-care, and on how a risk-based product categorization system will affect stakeholder groups, such as patients, consumers and industry. It was noted that the product categorization system should work in the interest of all stakeholder groups, with a focus on Canadians' health and safety as the foremost priority.

#### Modernized regulatory approach for food safety and nutrition

Participants were pleased with the Blueprint commitment to develop an efficient and responsive regulatory framework for food, and to minimize unnecessary delays in the pre-market decisions on novel foods and food additives. Nonetheless, some remarked that they would like more emphasis on food regulation modernization, and in particular, on the development of a food health claims framework.

#### Protecting the health and safety of Canadians

Participants noted that the Blueprint makes no mention of patient and consumer safety, and recommended that this be clearly articulated as a primary objective of Health Canada's renewal efforts.

### **Precautionary principle**

A number of participants noted the absence in the Blueprint of references to the importance of the precautionary principle in regulatory decision-making, and noted its continued usefulness when reviewing products intended to enhance health, as opposed to those designed for life-threatening situations.

### **Common drug review (CDR)**

Participants urged greater alignment and collaboration between Health Canada and its system partners, in particular the CDR.

### **Evidence-based decisions**

Participants cautioned that new regulatory frameworks should facilitate rather than hinder research and the generation of sound scientific evidence. Participants recommended that independent science be used by Health Canada more frequently to balance industry-funded science, and made requests for greater clarification of evidence requirements in order to facilitate the entry and innovation of small and medium-sized enterprises. There was also support for the national network of research centres for Real World Safety and Effectiveness that may be created as part of the National Pharmaceutical Strategy.

## Regional Report - Longueuil, Quebec

November 20, 2006

### Questions and answers

Questions posed by participants at the Longueuil meeting included:

- *how the Blueprint addresses the growing problem of access to drugs through the Internet*  
 HPFB personnel acknowledged that Internet pharmacies raise significant issues of compliance and enforcement. Health Canada has developed a foreign product advisory alert for those cases where pharmaceuticals that are not authorized in Canada are brought into the country, and continues to work with Canada Customs so that we can stop these products from entering.
- *how the Blueprint and especially the Progressive Licensing Framework will strengthen Health Canada's ability to monitor products once they are on the market and intervene if necessary when safety issues arise*  
 Branch officials acknowledged that, at present, the regulator can only take limited action in this area. However, the Progressive Licensing Framework would allow the Branch to monitor the product's risk-benefit profile on an ongoing basis. Blueprint initiatives are also focused on strengthening tools and capacity for post-market surveillance as well as compliance and enforcement capacity and tools.
- *how progress on the Blueprint initiatives will be measured and what will be the mechanisms for putting them in place?*  
 The Branch is working on a 5-year strategic plan that will incorporate Blueprint objectives, and set out a manageable timeframe for its implementation. In some cases, legislative changes will be necessary and will take more time, but most elements can be changed by regulatory or policy means. Other elements simply call for a change in the way the Branch works
- *how the Branch will promote public access to information and public participation in regulatory decision-making*  
 Last year, the Branch held two public forums, one on Cox-2 inhibitors and one on silicone gel-filled breast implants. These fora were important to opening the Branch's processes to the public. A Policy on Public Input is also under development, and will articulate more clearly when we should involve the public in our work and how to deal with the interests that people bring to the table. On the information side, the Branch is now publishing the *Summary Basis of Decisions* and launched the MedEffect website on adverse drug reactions. Consultations were held this summer on the disclosure and registration of clinical trials. These are all major steps forward in HPFB's transparency agenda.
- *how Health Canada will improve Adverse Drug Reaction reporting and, more generally, post market surveillance*  
 Health Canada is in the process of installing a new electronic database which will allow for a greater number of reports to be processed and analyzed. The Branch deals with 175, 000 reports annually,

and will also be working with international agencies to access ADR data from around the world. We also wish to increase reporting by health professionals, increase public education and make it easier for people to report. MedEffect is Health Canada's portal for accessing information on ADR.

- *given the Branch's current resource pressures, how it will fund its renewal efforts*

The renewal of HPFB's external charging scheme is essential to this challenge. Currently 20% of the Branch's budget comes from fee collection. This is one of the lowest levels among international regulators. Renewal of the Branch's cost recovery scheme will take up to 18 months but promises to make a significant difference in terms of HPFB's capacity. In addition, a program review is under way to make sure that our budget is in order and is being properly used.

## **Prepared interventions by participants – Key themes**

### **Consumer information and education**

Consumer information and education was frequently raised at the Blueprint session in Longueuil. Many participants pointed out that the Internet is often not the best way to reach people, especially those who are disadvantaged or have a low level of literacy. Participants recommended that Health Canada work with groups who can communicate information in simple language. Information for health professionals should also be a priority. Participants were also concerned about direct-to-consumer advertising of products, and urged Health Canada to be more assertive in enforcing the laws on drug advertising.

### **Food**

Participants pointed to the importance of the food industry in Canada and the need for a food regulatory modernization strategy. One participant felt that Canada should increase harmonization with the United States on the use of pesticides, and that food imports often do not meet Canadian standards, which can result in unfair competition. It was also suggested that the development of regulations on food additives and health claims be accelerated. Participants also encouraged efforts through regulation to provide more and better information about food to consumers, particularly immigrants, to help them make healthier choices.

### **Risk management**

Participants voiced concern about the concepts of risk management presented in the Blueprint, and on industry's influence on the risk management activities of Health Canada.

### **Post-market surveillance and adverse drug reporting**

Some participants suggested that ADR reporting should be mandatory for health professionals. All agreed that professionals had to be more aware of the need to report ADRs and to better explain risk factors to their patients. Health professionals also pointed to the need for "tracking tools" to identify and inform patients when there is a problem with a drug. One participant noted that Health Canada might need to provide funding to certain organizations in order to facilitate the public's ability to report.

Many felt that there is a need to distinguish between risk management and pharmacovigilance. Some suggested that Health Canada should monitor drugs at an international level to reduce the risk of disastrous effects, and that Health Canada should also have the authority to compel companies to do post-market clinical trials to ensure that products continue to be monitored for safety and effectiveness, once they reach the market.

### **Natural health products**

Some participants wanted natural health products (NHPs) to fall under many of the same regulatory requirements as pharmaceuticals. There was concern about the current state of implementation of the NHP regulations and licensing of products. Transition to the new regulations has led to confusion on the part of consumers and could have potentially unwanted health consequences. The lack of clarity around NHP guidelines, and an inspection program were also mentioned, as was the inadequacy of information on NHPs currently available to the public.

### **Product categorization**

Participants predicated their support for a new product categorization system on how products are defined and what level of risk is ascribed to each. Participants noted that there must also be mutual understanding among all on how products are categorized in order for the system to work. One participant also thought that there should be a specific classification for products used in “prevention.”

### **Openness and transparency**

All participants agreed that access to information improved the ability of consumers to make informed choices. Some participants noted the Blueprint commitment to improve public participation in policy development and the review process, and noted that the lack of capacity of patient and consumer groups was a growing problem. Some participants also pointed out that it might be useful to convene certain advisory panels where there is no industry presence.

### **Veterinary drugs**

Participants raised several issues related to the use of veterinary drugs, noting that some of the drugs used on animals end up in the food that we consume. In some cases, antibiotics which are not authorized for human use are prescribed to food-bearing animals, which can encourage human immunity to that particular antibiotic. Internet pharmacies direct advertising to consumers and the use of natural health products for animals were also identified as sources of problems for the veterinary sector.

### **Roles and responsibilities of health professionals**

Many participants felt that health professionals and academia could play a stronger role in the regulatory system. They expressed an interest in opportunities to do independent research on new indications that industry may not want to do; and in the provision of health professional expertise and research to Health Canada. Professionals would like Health Canada to fund independent research that will meet

consumers' needs, rather than industry, and would like Health Canada to support the medical publications. Academia could also have an increased role, given their connection to tomorrow's health professionals. It was suggested that Health Canada increase its use of research experts, patients and consumers on advisory committees.

## Regional Report - Ottawa, Ontario

November 21, 2006

### Questions and answers

Participants at the Ottawa session wanted to know:

- *how Health Canada will work with the provinces to strengthen surveillance capacity to obtain more information*  
Branch personnel indicated they had met with the provincial/territorial governments in September and agreed to more consistent interactions with each other on the regulatory system, along with other partners who have a role in this area. A key vehicle to achieve this is the National Pharmaceutical Strategy's Real-World Safety and Effectiveness initiative.
- *whether the Progressive Licensing Framework will also apply to natural health products and food*  
Although the Progressive Licensing Framework is currently being applied to pharmaceuticals and biologics, there is the potential to apply this framework to natural health products and food, as appropriate.
- *whether advertising will be included in the review of the Food and Drugs Act*  
Advertising of health products and food will be addressed within the legislative renewal process.
- *how the Blueprint will address specific populations, areas of unmet needs and rare disorders*  
These issues are being considered in the context of the Progressive Licensing Framework initiative, as well as the Blueprint objectives related to specific populations.

### Prepared interventions by participants – Key themes

#### Post-market surveillance

Participants lauded the idea of increasing post-market surveillance and implementing a comprehensive ADR process that is easy to use. Additionally, all felt that a feedback system from Health Canada to consumers is crucial to communicating safety concerns about health products. Participants also felt that adverse drug reactions should be monitored at an international level.

#### Interventions proportional to risk

Many participants supported the objective of interventions proportional to risk, but cautioned against over-regulation.

#### Protecting the health and safety of Canadians

Like those in other sessions, some participants felt there was insufficient emphasis in the Blueprint for Renewal on Health Canada's mandate to protect the health and safety of Canadians. Other participants felt that Health Canada should change some of its practices, including having branches and directorates

work together more closely, developing more educational campaigns to inform the public of health and safety issues, and increasing the transparency of Health Canada advisory committees.

### **International partnerships**

One participant noted that international partnerships should be a priority for Health Canada. Many others agreed that Canada should support international best practices in the area of regulation, while others were concerned about how “best practices” would be determined.

### **Evidence-based decisions**

Evidence-based decision-making was described by participants as the cornerstone of Health Canada’s work, and the Branch was encouraged to preserve the quality of its evidence-based decisions and decision-making processes. One participant pointed out that Health Canada should consider a wider range of evidence (beyond science alone) to help make evidence-based decisions.

### **Natural health products**

Participants voiced general concern about the implementation of the new regulatory regime for NHPs. One participant noted that homeopathic products represent a broad and complicated range of products, and should be regulated under one regulatory framework. Often, because some natural health products and foods do not fit neatly into existing categories, they fall into a “grey zone” in the regulations.

### **Product categorization**

Participants were concerned about the current “patchwork” of product categories and how that might affect consumers’ choice. One participant endorsed a consumer-centric approach to product categorization to ensure that consumers properly understand the categories. The product categories should also be consistent with a risk-based approach. Participants were also concerned about the effects of labelling a pharmaceutical or natural health product “low risk” as some consumers may think the product is entirely safe.

### **Life-cycle approach**

Participants supported a life-cycle approach, and noted it could benefit drug development, allowing pharmaceutical companies to provide new safety and efficacy data as it is generated.

### **Common drug review**

Concern was expressed that products approved by Health Canada (guided by considerations of safety, quality and efficacy) are essentially inaccessible when they are not recommended for public drug plan listing by the Common Drug Review, (guided by considerations of cost-effectiveness).

### **Medical devices**

One participant noted that the safety issues around the re-processing of single use devices and the licensing of diagnostic medical devices remain unresolved in Canada. It was suggested that specific regulations to govern how equipment is sold or ownership is transferred are needed.

## Regional Report - Vancouver, British Columbia

November 23, 2006

### Questions and answers

Vancouver session participants wanted more information on a number of issues, including questions on:

- *what criteria Health Canada will consider in developing its cost-recovery regime and how the public and industry stakeholders will be involved*

Health Canada will hold an extensive consultation process on fee revenues to determine exactly what the regime will look like and how stakeholders will be affected. Most importantly, Health Canada will continue to ensure that Canadians' health and safety remain the priority in the development of the new regime.

- *how Health Canada will support involvement for those stakeholders with limited capacity*

Health Canada has funded and will continue to fund public involvement for specific initiatives. Branch personnel noted that Health Canada's own capacity is a factor in making decisions about when and how to involve stakeholders.

- *how the Blueprint will improve coordination with the provinces and territories (P/Ts)*

Health Canada met with P/T regulatory authorities for the practice of pharmacy and medicine in June and P/T health ministries in September and agreed upon a mechanism to meet regularly and to work on a common set of issues. To date, P/Ts have been very receptive to key Blueprint objectives including a stronger post-market regulatory system and the development of a product lifecycle approach. HPFB will meet with P/T health ministries again early in March 2007 and P/T regulatory authorities in June 2007.

### Prepared interventions by participants – Key themes

#### Consumer information and education

Many participants supported initiatives that would educate the public on Health Canada's regulatory system, and suggested that Health Canada investigate the experiences of other countries in enhancing the role of consumers in the post-market regulatory system.

#### International cooperation and harmonization

Many participants expressed support for international regulatory cooperation, and encouraged international benchmarking to allow for greater competitiveness, improved market access and more opportunities for research. Memoranda of understanding between Canada and other countries were also encouraged, to avoid duplication and to access data available in other countries.

**Clinical trials**

Participants suggested that the roles and responsibilities that Health Canada plays in clinical trials should be better publicized to increase awareness. As well, participants encouraged clarification of the guidelines for clinical trials involving medical devices and NHPs. Participants also expressed support for the transparent disclosure of clinical trial data and sources of trial funding.

**Natural health products (NHPs)**

A number of participants were highly supportive of the review of NHP regulations, and expressed strong interest in being involved. The importance of having sufficient resources within Health Canada, both to amend and enforce the NHP regulations, was noted. One participant suggested defining NHPs under a separate act rather than, as is currently the case, including them under of the *Food and Drugs Act*. Participants also supported an NHP regulatory framework modelled on the risk-category based medical devices regulations.

**Post-market surveillance**

Participants supported a strengthened post-market regulatory system and better balance of resources between pre- and post-market regimes. As well, participants expressed support for strengthening the scientific infrastructure of Health Canada in both the pre- and post-market areas.

**Adverse drug reaction (ADR) reporting**

Some participants noted that greater funding for ADR reporting is required in order to strengthen capacity in this area. For example, it was suggested that Health Canada fund consumer organizations that work with patients, to ensure that they have the necessary information to participate in ADR reporting. Health Canada was encouraged to address some of the current limits on communicating product information because of confidentiality or privacy requirements, which some participants felt prevented Health Canada's ADR reports from being as comprehensive as they should be.

**Health promotion and disease prevention**

Participants noted that there is little emphasis in the Blueprint for Renewal on health promotion and disease prevention, and maintained that promoting good health is necessary in order to reduce pressures on Canada's health care system. It was recommended that the Blueprint for Renewal reflect the health promotion role of the regulatory system.

**Compliance and enforcement**

Participants supported improved capacity and stronger authorities for compliance and enforcement. In particular, some participants encouraged stronger measures in the area of direct-to-consumer advertising. Participants strongly supported innovative ways to encourage industry compliance with Health Canada regulations, rather than merely increasing fines, which were viewed as less effective.

### **Research ethics**

Participants noted that there are no national standards for research ethics across Canada. These participants encouraged Health Canada to address this through legislation and enforcement wherever possible.

### **Special access program (SAP)**

Participants pointed out that patients still depend on drugs withdrawn from the market, often for reasons unrelated to safety, and encouraged Health Canada to take this issue into account when reviewing the SAP.

## Regional Report - Edmonton, Alberta

November 24, 2006

### Questions and answers

Questions from Edmonton participants included:

- *whether Health Canada's approach to international cooperation is more focused on harmonizing with the international community or on a Canadian risk-based approach*  
The Branch intends to harmonize with international best practices wherever possible, but given that the health and safety of Canadians is HPFB's priority, any harmonization would first have to fit with the interests and objectives of our own Canadian regulatory regime.
- *how the concept of risk/benefit assessment links to the precautionary principle*  
Risk/benefit assessment and the precautionary principle are two interrelated concepts that will continue to guide Health Canada decision-making.
- *how a Progressive Licensing Framework will improve product safety*  
Health Canada knows more can be done to identify potential safety, quality and efficacy concerns, using post-market surveillance. The Progressive Licensing Framework will help us better anticipate risks earlier in product development and practically monitor them once products are on the market. Working with other regulators, both within Canada and internationally, will help improve risk management and safety monitoring as well.
- *how Health Canada will close the gap between its role in evaluating the safety and efficacy of health products, and the CDR's mandate to analyze the cost-effectiveness of health products*  
Branch officials noted that this gap will never be fully closed. The roles of the two organizations are fundamentally different and there will always be some structural differences. Health Canada will, however, continue to work with the CDR to strengthen communication and cooperation on scientific issues.

### Prepared interventions by participants – Key themes

#### Regulatory Process

Many participants were concerned about the slowness and cumbersome nature of the regulatory process, noting this sometimes forces Canadians to seek access to drugs in other countries, rather than waiting for drugs to be approved at home.

#### Common drug review (CDR)

The disconnect between the approval of rare drugs by Health Canada and recommendations regarding listing of those drugs by CDR was noted by a number of participants, who encouraged Health Canada to focus on moving towards a more integrated system. Participants maintained that a range of evidence,

beyond cost-effectiveness, should be considered in making CDR recommendations on drugs for rare diseases, including scientific evidence, real world experience, quality of life data, and case studies.

### **Consumer information and education**

Participants noted that transparency and openness is a two-way process, and that information should be provided and taken into consideration by both Health Canada and stakeholders. The importance of education to consumers and health care providers was highlighted, and Health Canada was encouraged to ensure that stakeholders know how to access information on the Blueprint and other regulatory initiatives. As well, participants encouraged Health Canada to engage consumers whenever decisions will affect them.

### **Veterinary drugs**

Participants expressed support for applying a product life-cycle approach to veterinary drugs as a possible means of improving food safety and consumer protection, as well as improving timely access. Participants also urged Health Canada to address current problems created through lack of alignment between federal and provincial legislation.

### **Natural health products (NHPs)**

Participants supported HPFB's efforts to communicate on the review of NHP regulations. Participants noted the difficulty that industry has experienced when trying to determine product classification. Health professionals underscored their need for information on NHPs to be able to act in patients' and consumers' best interest. It was suggested that Health Canada collaborate with stakeholders to provide information on NHPs to health professionals, industry and the public.

### **Clinical Trials**

Participants reminded Health Canada of its responsibility to ensure that clinical trials are conducted in a safe manner, citing the research and development programs in the United States as a possible approach that Health Canada could consider.

### **Coordination with provinces/territories**

Participants noted the importance of an integrated system, and in working with the provinces/territories. Participants encouraged these partnerships in order to address the inconsistencies in regulatory frameworks.

### **Specific populations**

Participants supported stronger Health Canada leadership on health and safety issues affecting specific populations. Participants suggested that the "terminally-ill" sub-population be added to the list of specific populations that will be addressed in the development of regulatory policy.

### **Orphan drug policy (ODP)**

It was noted that Canada is the only developed country in the world without an ODP, and noted that, in the absence of such a policy, the existing Special Access Program is an important mechanism for accessing life saving drugs. Participants urged Health Canada to develop and adopt an ODP.

### **Cost Recovery**

Some participants noted that small to medium-sized enterprises may find additional or higher fees a challenge, and requested that these enterprises be taken into account when making changes to fee structures.

## 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.

## Participant Organizations

### Toronto Participants—November 3, 2006

- Canadian Association for Pharmacy Distribution Management
- Canadian Association of Chain Drug Stores
- Canadian Association of Importers and Exporters
- Canadian Association of Naturopathic Doctors
- Canadian Association of Professional Regulatory Affairs
- Canadian Cosmetic, Toiletry and Fragrance Association
- Canadian Council of Grocery Distributors (Toronto Office)
- Canadian Environmental Law Association
- Canadian Generic Pharmaceutical Association
- Canadian Institute of Food Science and Technology
- Cantox Health Sciences International
- Consumers Council of Canada
- CropLife Canada
- Institute for Safe Medication Practices (Canada)
- MEDEC
- Pharmaceutical Advertising Advisory Board
- University of Toronto – Faculty of Medicine – Department of Nutritional Sciences
- University of Toronto (The Leslie Dan Faculty of Pharmacy)
- Women and Health Protection

### Halifax Participants—November 6, 2006

- Atlantic Health Promotion Research Centre (Dalhousie University)
- BioNova (The Nova Scotia Biotechnology and Life Sciences Industry Association)
- College of Physicians and Surgeons of Nova Scotia
- Dalhousie University (Faculty of Health Professions, College of Pharmacy)
- Dalhousie University (Health Law Institute)
- Herbalists Association of Nova Scotia
- Memorial University of Newfoundland (Faculty of Medicine)

## Participant Organizations

- New Brunswick Pharmaceutical Society
- Nova Scotia Association of Health Organizations
- Policy Link New Brunswick
- Réseau société en français, Nouvelle-Écosse
- University of Prince Edward Island (Institute for Nutrisciences and Health (NRC-INH))

### Winnipeg Participants—November 10, 2006

- Ag-West Bio Inc.
- Alliance for the Prevention of Chronic Disease
- Canadian Women's Health Network
- Consumers' Association of Canada (Manitoba Branch)
- Health Care Products Association of Manitoba
- Manitoba Centre for Health Policy
- Saskatchewan College of Pharmacists
- Richardson Centre for Functional Foods and Nutraceuticals
- Saskatchewan French Health Services Network

### Longueuil Participants—November 20, 2006

- Canadian Natural Products Association
- Coalition des organismes communautaires québécois de lutte contre le sida
- Collège des médecins du Québec
- Conseil de la transformation agroalimentaire et des produits de consommation
- Fédération des Professionnelles
- Héma-Quebec
- Option Consommateurs
- Ordre des médecins vétérinaires du Québec
- Ordre professionnel des diététistes du Québec
- Union des Consommateurs
- Université de Montréal (Faculté de pharmacie)
- Université du Québec à Montréal (Faculté des sciences de l'éducation, Département de kinanthropologie, Programme de recherche sur la chaîne des médicaments)

## Participant Organizations

- Université Laval (Institut des nutraceutiques et des aliments fonctionnels)

### **Ottawa Participants—November 21, 2006**

- Advertising Standards Canada
- BIOTECCanada
- Canadian Blood Services
- Canadian Consumer Speciality Products Association
- Canadian Council of Food and Nutrition
- Canadian Healthcare Association
- Canadian Homeopathic Pharmaceutical Association
- Canadian Meat Council
- Canadian Medical Association
- Canadian Pharmacists Association
- Canadian Society of Hospital Pharmacists
- Centre for Science in the Public Interest
- Consumers' Association of Canada
- Dairy Farmers of Canada
- Direct Sellers' Association
- Heart and Stroke Foundation of Canada
- NDMAC
- Retail Council of Canada
- Rx&D (Canada's Research-based Pharmaceutical Companies)

### **Vancouver Participants—November 23, 2006**

- BC Biotech
- British Columbia Medical Technology Industry Association
- British Columbia Transplant Society
- Canadian Health Food Association
- Canadian HIV Trials Network
- Pharmawatch
- UBC Faculty of Medicine, Department of Anesthesiology, Pharmacology (Therapeutics Initiative)

## Participant Organizations

- Vancouver Chinatown Merchants Association

### **Edmonton Participants—November 24, 2006**

- Alberta Cord Blood Bank
- Alberta Veterinary Medical Association (AVMA)
- Best Medicines Coalition
- BioAlberta
- Canadian Animal Health Coalition
- Canadian Organization for Rare Disorders
- Canadian Patient Safety Institute
- Complimentary & Alternative Medicine Education & Research Network of Alberta (CAMera)
- University of Alberta (Faculty of Law, Health Law Institute)
- Western Canadian Functional Food and Natural Health Product Network (WCFN)