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Health Products and Food Branch
Public Involvement Annual Performance Report

2004-2005

Canada

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Winter 2006

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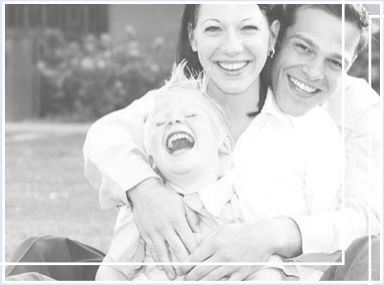

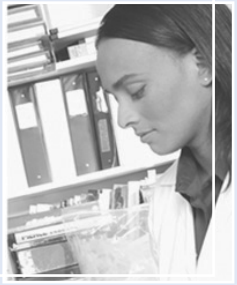

Health Products and Food Branch
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Executive Summary

One of Health Canada's key priorities is a commitment to greater transparency and openness. The Health Products and Food Branch (HPFB) of Health Canada takes an approach to public involvement that reflects this commitment. We integrate the principles of transparency and openness through public involvement activities by revealing more of our processes and activities to the public and building open relationships with our partners and stakeholders.

This annual report provides an overview of the various HPFB activities undertaken in 2004-2005 to involve the public in our decision-making processes.

HPFB applies a flexible approach to ensure the most appropriate method is used to involve the public. This flexibility enables us to select a method based on the purpose of the activity and the desired outcome. In some cases, we use a combination of methods to solicit meaningful feedback.

A total of 168 public involvement activities were conducted in 2004-2005. Of these, 102 were conducted on a per-issue basis and these covered 51 different topics. The majority of topics related to the policy development process, closely followed by issues related to the regulatory process. The primary objective for these activities was to gather information, which, in most cases, was used to select a strategy to address an issue within the Branch's mandate.

Most of the activities conducted on a per-issue basis were written input such as, mail-outs for feedback, web postings for feedback and publication in *Canada Gazette* Part I. Twenty-one were face-to-face meetings, such as workshops and focus groups.

The remaining 66 activities used ongoing Branch mechanisms to involve the public. Thirty-nine involved advisory committees, including the Branch's Advisory Committee on Management (ACM) and Public Advisory Committee (PAC), and several scientific and technical advisory committees.

Each activity provided the Branch with new perspectives and knowledge of the topics at hand. These perspectives were directly reflected in modified regulations, guidance documents, directives, policies, and approaches. Through this report and other assessments, we aim to communicate how we use the input we receive, consider our successes and areas for improvement, and continually refine our approach to public involvement to meet the needs of the Branch and those of our stakeholders.

1. Introduction

1.1 About This Report

This is the first annual report on public involvement activities conducted by the Health Products and Food Branch (HPFB). It covers the period between April 1, 2004 and March 31, 2005.

The Office of Consumer and Public Involvement (OCAPI), an office within HPFB, prepared this report with input from HPFB directorates and offices. OCAPI welcomes your comments on the information contained in this report. If you would like more information, or if you would like to complete an evaluation of this report, please see Appendices E and F, respectively.

1.1.1 Purpose

The purpose of this annual report is to communicate the Branch-wide picture on the diversity of public involvement activities we conducted in 2004-2005 and to demonstrate our ongoing commitment to involving the public in HPFB's decision-making processes.

Reporting on Branch activities also helps us to monitor trends over time, including the topics we addressed, the stages at which we involved the public in the decision-making process, the methods we used, and the groups we invited to participate. This information helps us to align our activities with departmental and federal guidelines and priorities.

1.1.2 Scope

This document reflects results from public involvement activities led by HPFB, including those initiated in response to departmental directives. This report does not include our participation in public involvement activities led by other Health Canada branches.

1.2 What We Do

HPFB's mandate is to take an integrated approach to managing the health risks and benefits related to health products and food by

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

To fulfill our mandate, we evaluate the safety, quality and effectiveness of drugs, vaccines, medical devices and other therapeutic products, including natural health products, available to Canadians. We also monitor the safety and quality of the Canadian food supply.

1.3 Our Commitment to Public Involvement

Canadians want to be empowered to make informed decisions related to their health and to hold directly accountable those who make health and safety decisions on their behalf. Public involvement activities offer Canadians the opportunity to have a role in decision-making processes and have their voices heard. Their unique perspectives, experiences and insights are vital contributions that enable Health Canada to make fully informed regulatory decisions.

As a science-based, multidisciplinary regulator and policy-maker, HPFB supports federal requirements to effectively involve the public in our decision-making processes and is accountable for how input received from the public is used. The *Government of Canada Regulatory Policy* requires that regulators ensure that "Canadians [be] consulted, and that they have an opportunity to participate in developing or modifying regulations and regulatory programs."[1]

[1] *Government of Canada Regulatory Policy*, Privy Council Office, November 1999, p. 3.

Public involvement is an important component of the work that we do, from developing policy and regulations to creating and implementing programs. One of the underlying principles described in the *Health Canada Decision-Making Framework* is the importance of involving interested and affected parties in the Department's decision-making processes. Health Canada's Public Involvement Continuum (see Appendix A) illustrates the five levels of public involvement and influence in the Department's decision-making processes to which our public involvement activities correspond.

1.3.1 Transparent and Open Communications

By revealing more of our processes and activities to the public and building more open relationships with our partners and stakeholders, the Department aims to achieve mutual understanding. HPFB's approach to public involvement reflects this commitment by providing access to information about how we conduct our business and how decisions are made. Through our public involvement activities, we integrate the principles of transparency and openness within our business practices.

1.3.2 Our Vision for Public Involvement

At the branch level, the *HPFB Public Involvement Framework (February 2005)*[2] defines our vision for public involvement:

The Health Products and Food Branch will have mutually beneficial relationships with the public. While respecting our regulatory responsibilities, the Branch will be open, transparent and accountable in our work, and integrate stakeholder input into our decisions. The Branch will improve stakeholder trust and confidence in the regulatory system.

Involving the public is one of our key priorities and provides the context within which we pursue our work. The Office of Consumer and Public Involvement (OCAPI) supports the work of the Branch by providing information and opportunities to the people of Canada to become meaningfully involved in the decision-making processes that result in HPFB's priorities, policies and programs.

In the future, the Branch aims to create even more meaningful and appropriate opportunities for our stakeholders to participate in our decision-making processes.

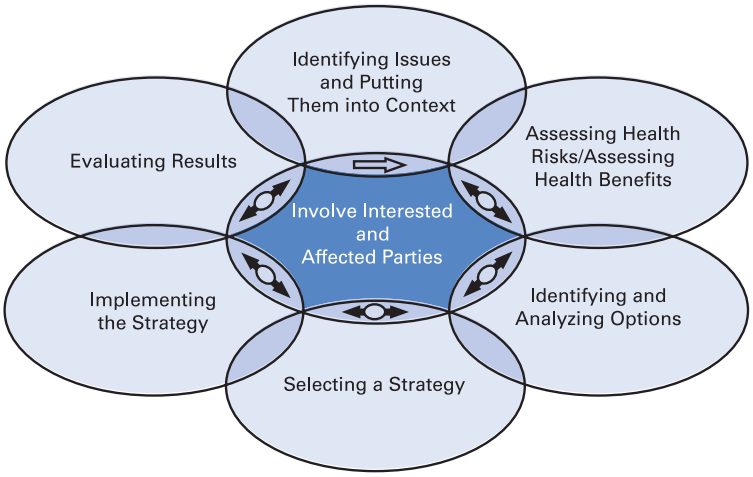
1.3.3 Determining When to Consult and How

The Branch solicits input from the public both on a per-issue basis and through a variety of ongoing mechanisms. Appendix B provides a glossary of the methods we use to involve the public.

HPFB applies a flexible approach to ensure the most appropriate method is selected to involve the public in our decision-making processes. This flexibility enables us to select a method based on the purpose of the activity and the desired outcome. In some cases, we use a combination of methods to solicit meaningful feedback.

Our decision-making process for policy and regulatory development is divided into six stages. We can involve the public in one or more of these stages.

Decision-Making Framework (Health Canada)



Many factors influence our decision to consult, the appropriate stage at which we decide to carry out consultations, the extent of involvement required, and the appropriate method to use. We also consider the influences and interests outside government that have a bearing on the issue.

[2] The HPFB Public Involvement Framework is available at <http://www.hc-sc.gc.ca/hpfb-dgpsa/ocapi-bpcp/piframework_cadrepp_e.html>.

1.3.4 Selection of Participants

HPFB public involvement activities are targeted to specific groups of participants based on the nature of the topic and the type of input we need. Some issues require highly specialized or technical input, while others benefit most from the perspective of a wide range of participants. In all selection processes, we aim to ensure that all interested or affected groups are represented.

1.4 Definitions

Activities conducted on a per-issue basis are activities focused on soliciting feedback on a particular issue at a single point in time through the most appropriate and effective means available (see Appendix B). Activities conducted on a per-issue basis can make use of face-to-face or other types of activities to obtain the input required.

Consumer groups represent users or purchasers of the products or services of the Branch or Health Canada and are a segment of the public (see **Public**).

Continuum of public involvement refers to the full range of public involvement in issues of public concern. The *Health Canada Policy Toolkit for Public Involvement in Decision Making* refers to five levels of public involvement and pinpoints an array of public involvement methods along a continuum. Communications methods are at the "low end," consultation is in the "mid-range," and citizen engagement is at the "high-end" of the public involvement continuum (see Appendix A).[3]

Health professional associations represent physicians, nurses, pharmacists, dentists, hospital administrators, natural health practitioners, alternate medicine practitioners, and other types of health professionals. They are also a segment of the public (see **Public**).

Ongoing mechanisms refer to permanent committee and bilateral and association meetings held on a regular basis at predetermined intervals to solicit feedback and advice on HPFB issues and initiatives, discuss regulatory issues, and enhance co-operation and collaboration with consulted groups.

Openness is inviting, hearing, considering, and sharing information in the conduct of HPFB's business.

Patient groups represent individuals who require or who are under medical care and are a segment of the public (see **Public**). A patient may also be a consumer; however, not all consumers are patients.

Public is defined broadly and inclusively to cover all the individuals or groups who may be interested in or affected by the decision-making body. The definition does not require the certainty that any individual or group has such an interest, just that they may have. The public therefore includes consumers, patients, professionals, academia, industry, and the groups that represent them.

Public involvement refers to interactions between the public and the decision-making body (e.g., Health Canada). Public involvement methods refer to a broad range of strategies and methods used to inform interested members of the public, accord them a voice on issues of public concern, and include them in decision-making processes relating to these issues.[4] Public involvement methods include surveys, focus groups, feedback on discussion documents, public meetings, dialogue, workshops, advisory boards, and partnerships (see **Continuum of public involvement** and Appendix A).

Stakeholders are individuals, groups, or organizations that are affected by or interested in an issue or policy. Stakeholders, interested parties, and affected parties are segments of the public consisting of those that the Branch knows are interested in the specific subject matter, based primarily on previous experience with them. The Branch interacts regularly with different types of stakeholders such as health professionals, academia, industry, patients, and others.

Transparency is facilitating access to and understanding of the information processes HPFB uses to conduct its business.

[3] Health Canada Policy Toolkit for Public Involvement in Decision Making, Corporate Consultation Secretariat, 2000.

[4] Ibid.

2. Public Involvement Activities onducted on a Per-Issue Basis

HPFB conducted 102 activities on a per-issue basis in 2004-2005, covering 51 different topics. The majority of topics related to the policy development process (24), closely followed by issues related to the regulatory process (21). See Appendix C for a complete list of topics addressed on a per-issue basis.

2.1 Our Objectives

HPFB conducted these activities to

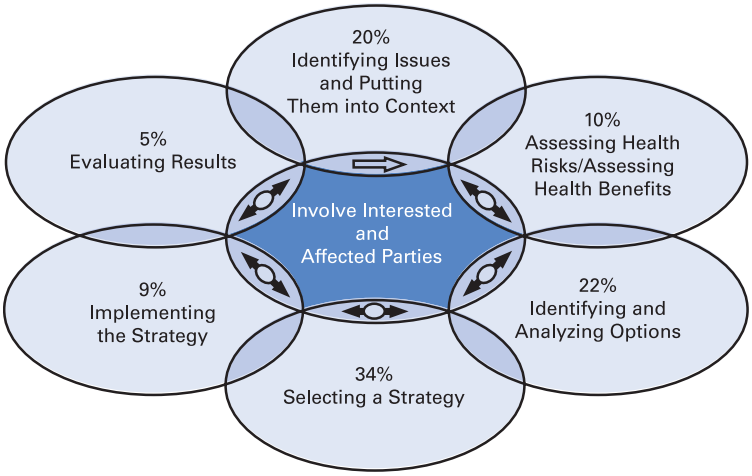
- build stakeholder capacity;
- communicate progress, discuss issues and identify barriers to implementation of various HPFB initiatives;
- clarify Health Canada expectations;
- obtain expert opinion;
- invite comments on proposed changes to policy and regulations;
- gather input on draft guidance documents, directives, policies, and other documents;
- gain a better understanding of Canadian consumer views and behaviours; and
- provide specific groups of stakeholders with an opportunity to learn more about HPFB and participate more meaningfully in our decision-making processes.

These activities are aligned with the following objectives described in Health Canada's Public Involvement Continuum (see Appendix A):

2.2 When We Consulted and How

During policy and regulatory development, and in other areas such as program development, HPFB involved the public in various stages of our decision-making processes. Most of the activities were initiated near the mid-point of the process to assist HPFB in selecting a strategy to address an issue within the Branch's mandate. Activities were distributed among the six stages as illustrated below.

Public Involvement Activities and the Decision-Making Framework

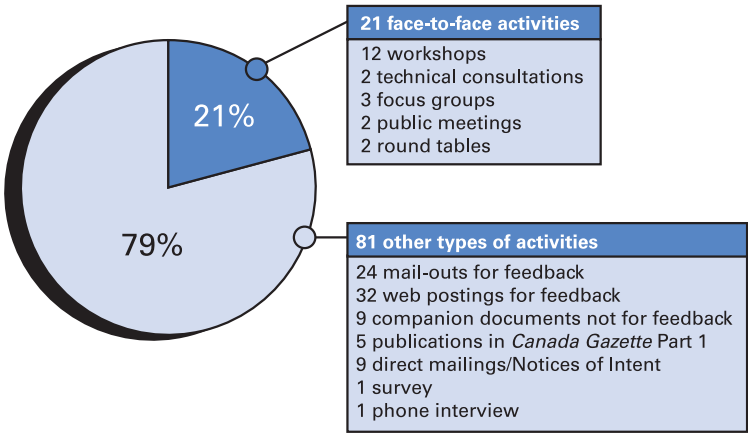


Note: For 16 of the activities, the corresponding stage of the DMF was not identified. Most of these activities represent pre-*Canada Gazette* Part 1 publications, publications in *Canada Gazette* Part 1, mail-outs for feedback and web postings.

Level	Objective	Examples of Types of Activities	Number of Activities
1	Inform or educate	Notices of Intent, companion documents	18
2	Gather information	Mail-outs for feedback, web postings for feedback, *Canada Gazette* Part 1, focus groups, surveys	66
3	Discuss	Workshops, technical consultations	16
4	Engage	Round tables	2

A range of public involvement methods was used to achieve the objectives of the 102 public involvement activities conducted on a per-issue basis.

Types of Public Involvement Activities Conducted on a Per-Issue Basis



2.3 Case Studies of Public Involvement Activities

Each public involvement activity held in 2004-2005 provided the Branch with needed input and a valuable opportunity for learning. Given the number and range of these, describing the context and results for each one would be beyond the scope of this report. The following three case studies were selected to demonstrate the diversity of activities conducted by the Branch, what we learned, and the impact on our work. Each highlights a different level of involvement, from gathering information and opinions (Case Study 1), to enabling in-depth discussion and involvement (Case Study 2), to engaging stakeholders in program development (Case Study 3).

2.3.1 Case Study 1: Focus Groups on Food Fortification

A decision to review Health Canada's policy on food fortification — the addition of vitamins and minerals to food such as vitamin D to milk or thiamine to breakfast cereal — led to broad consultation with stakeholders and culminated in a series of focus groups in July 2004. The focus groups were designed to determine what consumers thought about allowing manufacturers to fortify foods at their discretion and the role Health Canada should play to protect consumer health and ensure consumer choice. Results from the focus groups were instrumental in the development of the policy proposal that the Branch released in March 2005.

The policy review began with consultations with external stakeholders, such as academia, food manufacturers, consumer organizations, and public health associations, but came to a stalemate when stakeholders could not reach a consensus on the limits that should be applied to food fortification. At that point, Health Canada turned to focus group testing to find out what consumers wanted and how the availability of more fortified foods would affect their food choices.

Twenty-three focus groups were conducted in Vancouver, Calgary, Winnipeg, Toronto, Trois Rivières, Montreal, and St. John's. To ensure that Health Canada heard a wide range of views, the focus groups included seniors, teenagers, parents with children and people at the low and high ends of the socio-economic scale.

Participants expressed a qualified acceptance of the fortification of foods at the discretion of manufacturers, providing Health Canada set the limit and range on the nutrients to be added. The participants were concerned about the effect fortification would have on the price and taste of the food. They wanted fortified foods to be clearly labelled and assurance that Health Canada would monitor manufacturers' claims, and the quality or source of the nutrient. They also requested nutritional information to make proper food choices.

The focus groups proved to be an effective way to draw out the attitudes, feelings, beliefs and experiences of the participants, and the final policy proposal reflects their concerns. While it permits discretionary fortification of certain foods and an expanded list of special purpose foods, such as meal replacements, the policy sets limits on the amounts and types of nutrients to ensure consumer safety, and requires clear labelling to indicate whether a food is fortified.

Health Canada informed all stakeholders and the media of its proposed policy release in March 2005 so that anyone interested could have another chance to influence its content prior to its publication in *Canada Gazette* Part I by March 2006.

2.3.2 Case Study 2: Consultation Workshop on Summary Basis of Decision Documents

In June 2004, a wide range of stakeholders was invited to participate in a consultation designed to influence the direction of a new initiative to increase transparency in the review and approval process for drugs and medical devices. In a consultation workshop hosted by HPFB, participants were invited to shape the direction of the initiative as well as the content and format of the documents to be published in support of that effort.

Attended by health care professionals, patient and consumer organizations, pharmaceutical companies, and members of the academic, research, and regulatory communities, the two-day workshop demonstrated the Branch's commitment to ensuring that its policy development is inclusive and its decision-making transparent.

The proposal discussed at the workshop was the Summary Basis of Decision (SBD) initiative. The SBD document places the scientific and risk/benefit-based considerations that go into Health Canada's decision to authorize the marketing of a drug or medical device into the public domain. HPFB proposed implementing the SBD initiative in phases, starting with the development and publication of SBD documents related to the authorization of New Drug Submissions for New Active Substances, and a subset of Class IV medical device applications.

Workshop participants came to better understand the potential and the limitations of the SBD initiative through the workshop presentations, table discussions, breakout sessions, and plenary reporting. To support informed treatment choices, they recommended that the SBD documents respect proprietary data and complement other sources of information without duplicating them.

Other recommendations included linking to other documents, such as product monographs, pre-clinical and clinical studies, adverse reaction reports, and so on; publishing the documents on the Internet; and publishing information related to drug submissions that are denied or withdrawn. As a result of their input, HPFB committed to publishing a one-page summary of the authorization for a drug or medical device shortly after authorization (Notice of Decision [ND]), and added supporting information to the SBD documents.

Feedback from the workshop was an essential part of the development of the first phase of the initiative, which was launched on January 1, 2005. When phase one has been in place for about 12 to 18 months, the public will once again be invited to participate by evaluating the first phase and helping to determine the course of phase two.

2.3.3 Case Study 3: Pilot Information Session for Patients and Consumers

In March 2005, HPFB hosted an innovative pilot session to ensure patients and consumers have the information and support they need to better participate in decision-making about the risks and benefits of health products and food. The pilot information session, the first of its kind at Health Canada, marked a significant milestone in a year-long process of consultations, assessments, research, and surveys with patients and consumer organizations across Canada.

Developed by HPFB in collaboration with a Joint Steering Group made up of 16 patient and consumer representatives from across Canada, the session provided information about HPFB tailored to the needs of patients and consumers. The session focused on introducing the decision-making process used by the Branch to review drugs for safety before they are authorized for sale in Canada; clarifying the roles of federal, provincial and territorial governments in the health system; and explaining the science-based work at HPFB.

About 50 patient and consumer representatives participated in the daylong session, which was held in Gatineau and broadcast live to groups in Moncton, Winnipeg and Toronto by the Internet and teleconference. Interested individuals were also able to participate from anywhere in Canada by hooking in from their home or office.

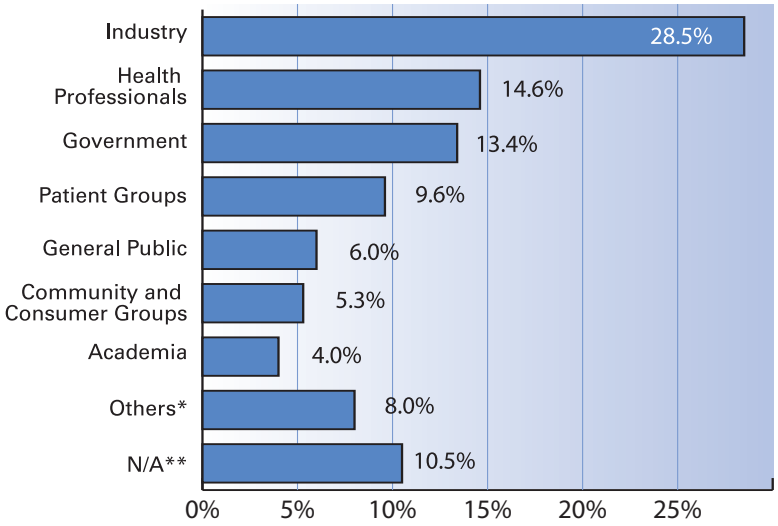
The premiere information session marked the inauguration of a series of sessions planned for the future. Participants were invited to evaluate the information provided in the session as well as the means of its delivery. The 36 participants who completed an evaluation reported benefiting from the question and answer session, the opportunity to network with other concerned representatives of the public, and the access to experts, including the Health Minister and HPFB's Assistant Deputy Minister. Participants also gave high ratings to the self-learning workbook, *Access to Safe and Effective Medicines*, received as part of an information package prior to the session.

HPFB is using the feedback, especially the suggestions for improvement, to shape the upcoming information sessions. The Branch is working to build on the success of the pilot and extend the reach of the initiative to other areas in Canada and a broader range of patients and consumers.

2.4 Participant Representation and Selection

A total of 4,162 individuals were invited to participate in activities conducted on a per-issue basis in 2004-2005. [5]

Invitation to Participate in Activities by Stakeholder Group



* Includes veterinary associations, regulatory bodies, non-regulatory bodies, international bodies, computer vendors, cell-tissue-organ and blood organizations, advisory committee members and livestock producers.
** Information not available

In some cases, existing lists of stakeholders were consulted to select appropriate participants. In others, an assessment was made to identify those who would be affected by or would have an interest in a particular issue. Participant selections were made with the following objectives in mind:

- Involving those affected by the issue
- Involving those with an expressed interest in the issue
- Contributing to effective decision and policy-making
- Gaining an understanding of stakeholder concerns
- Achieving balanced representation
- Increasing transparency
- Obtaining expert opinion

2.4.1 Location

Of the 21 face-to-face activities, 12 were held only in the National Capital Region (NCR). Six consultations were held in other cities across Canada:

- The *HPFB Public Involvement Framework* workshop's was held in Ottawa, Edmonton, Vancouver, Winnipeg, Toronto, Moncton, Fredericton, Truro, Charlottetown, Longueuil and Saskatoon.
- The Pilot Information Session for Patients and Consumers was held in Gatineau and broadcast in Winnipeg, Toronto and Moncton.
- The Interactive Nutrition Label and Quiz — Qualitative Research focus groups were held in Toronto, Montreal, Winnipeg and Calgary.
- Focus-testing on Canadian consumer perspectives on food fortification was held in Calgary, Vancouver, Winnipeg, Montreal, Toronto, Trois Rivières and St. John's.
- The Third Workshop on Food Allergen Methodologies was held in Vancouver.

[5] This figure includes individuals to whom information was submitted for feedback and those who attended face-to-face sessions.

- The consultations on the New Regulatory Framework for the Safety of Cells, Tissues and Organs (CTOs) were held in Toronto, Edmonton, Halifax and Montreal.

HPFB is continually exploring options to extend the reach of our public involvement activities to locations across Canada. Teleconferencing and Internet-based technologies such as "webinars" and online workspaces provide options for participants to connect remotely with the Branch. Initiatives such as web postings for feedback and mail-outs also provide the Branch with valuable feedback from across the country.

In all cases, HPFB considers the purpose and desired outcome of the activity to determine the most appropriate method to involve the public. Consideration is also given to ensure that the selected method is accessible to all participants.

2.5 Cost

The total estimated cost of public involvement activities conducted on a per-issue basis in 2004-2005 was $702,765.00. This estimate does not include staff salaries for those involved in the planning and preparation of public involvement activities.

Face-to-face consultations totaled an estimated $657,980.00, or almost 94 percent of the total budget for activities conducted on a per-issue basis. Costs for face-to-face activities depended on the number of participants, travel requirements, any required facilitation and simultaneous translation, and the reporting requirements.

Non-face-to-face activities accounted for $44,785.00 of allocated funds. The estimated costs for the majority of non-face-to-face activities undertaken during the reporting period ranged from $200.00 to $4,500.00 for pre-*Canada Gazette* Part 1 publications, mail-outs for feedback, web postings, notices and phone interviews. One activity was estimated at $25,000.00, the cost of which was largely attributed to report writing to synthesize and use the results.

2.6 Outcomes

Following each activity, HPFB consolidated the input received and assessed the impacts on the proposed policy, regulatory or other processes. In some cases, the input received confirmed our strategies or directions; in others, participants identified additional priority areas and new issues for consideration; still others prompted plans for additional consultations.

Each activity provided HPFB with new perspectives and knowledge of the topics at hand. This perspective was directly reflected in modified regulations, guidance documents, directives, policies and approaches.

3. Public Involvement Activities Conducted Using Ongoing Mechanisms

3.1 Overview

HPFB gathers input and obtains advice from a number of committees and other groups that meet on an ongoing basis. Made up of external members, these committees are valuable independent sources of information. In many cases, these groups are the only sources that can provide HPFB with leading-edge knowledge of relevant issues. HPFB's use of external advisors also provides the Branch with opportunities to communicate its policies and increase the transparency of the decision-making process.

HPFB solicited feedback and advice, discussed regulatory issues and enhanced co-operation and collaboration through 31 bilateral meetings and 39 advisory committee meetings in 2004-2005. Appendix D describes the roles of the committees and other consultative bodies with which the Branch met during this reporting period.

3.2 Our Objectives

Regular meetings with various groups help to ensure that participants are appropriately informed of the Branch's activities, that their views are heard, and that we are held accountable for the work we do. While each meeting is held to meet a specific objective, we generally aim to achieve one or more of the following goals:

- Receive medical, technical, scientific or other expert advice and recommendations on policy development or regulatory issues related to products regulated by HPFB
- Request advice and guidance on the planning, development, delivery and evaluation of HPFB programs
- Ensure that HPFB and our stakeholders have the same understanding of relevant issues
- Discuss issues of mutual interest, including regulatory issues, and share information and expertise
- Solicit advice from a wide variety of stakeholders, including consumers and the public, on major issues and initiatives
- Enhance co-operation and collaboration with consulted groups

3.3 When We Consulted and How

3.3.1 Bilateral Meetings

Directorate officials meet with industry and health professional associations to discuss and consult on regulatory issues of mutual interest, share information and expertise, and when appropriate, responsibilities. Some meetings are held regularly (one to four times per year), while others are conducted as needed to develop relationships or to discuss specific issues.

HPFB held 31 bilateral meetings in 2004-2005. As part of the Branch's regular engagement process with stakeholder groups to discuss regulatory issues, HPFB held four bilateral meetings with health professionals. These meetings were held with the Canadian Society of Nuclear Medicine, the Canadian Medical Association, the National Association of Pharmacy Regulatory Authorities, and the Canadian Pharmacists Association.

Bilateral meetings were also held with the following industry organizations:

- Advertising Preclearance Agencies (1 meeting with the Pharmaceutical Advertising Advisory Board)
- BIOTECanada (3 meetings)
- Canada's Medical Device Technology Companies (MEDEC) (3 meetings)
- Canada's Research-Based Pharmaceutical Companies (Rx&D) (4 meetings)
- Canadian Association for Pharmaceutival Distribution Management (CAPDM) (1 meeting)

- Canadian Consumer Specialty Products Association (1 meeting)
- Canadian Generic Pharmaceutical Association (4 meetings)
- Canadian Homeopathic Pharmaceutical Association (1 meeting)
- Direct Sellers Association (1 meeting)
- Groupement provincial de l'industrie du médicament (2 meetings)
- NDMAC (2 meetings)
- Nuclear Medicine Alliance (3 meetings)

3.3.2 Advisory Committee Meetings

HPFB has established a number of advisory committees that provide advice and, in some cases, act as sounding boards to the Branch and to other Health Canada officials as they carry out their work.

HPFB held 39 meetings with 20 advisory committees in 2004-2005.

Branch-Wide Committees (5 meetings):

- **Advisory Committee on Management (ACM) (2 meetings)**: The ACM met to discuss the Therapeutic Access Strategy, look-alike sound-alike products, transparency and public engagement, the Office of the Auditor General (OAG) audit of the Medical Devices Program and associated action plan, and the disclosure of clinical trial information.
- **Public Advisory Committee (PAC) (3 meetings)**: The PAC met to provide advice on Somatic Cell Nuclear Transfer (SCNT) cloning and its use in food-producing livestock animals, plant molecular farming, and the *Health Canada Framework for Biotechnology;*

  HPFB's integrated approach to planning, reporting and performance management for 2004-2005; antimicrobial resistance; the results of the Summary Basis of Decision workshop (see Section 2.3.2); and issues related to the application of user fees; and

  innovation in drug regulation, use of foreign drug reviews, ensuring a safe blood supply.

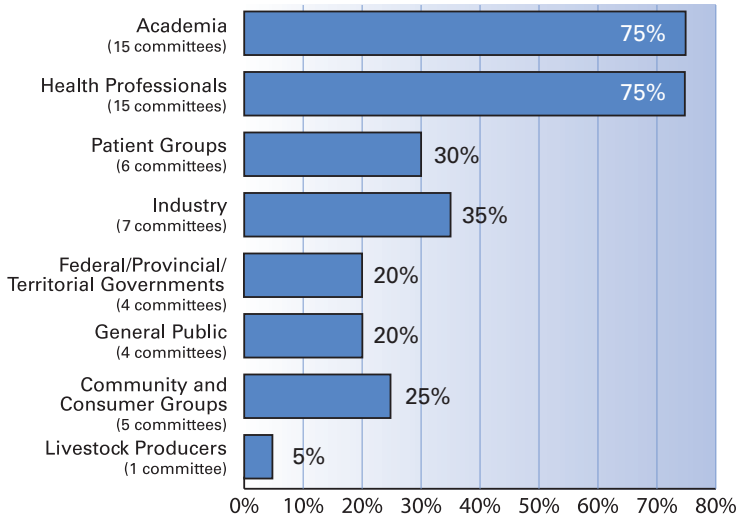
Other Committees (34 meetings):

Meetings were also held with the following groups:

- Scientific Advisory Committees (SAC) on HIV Therapies (1 meeting)
- SAC on Bioavailability and Bioequivalence (1 meeting)
- SAC on Medical Devices Used in the Cardiovascular System (2 meetings)
- Expert Advisory Committee (EAC) on Blood Regulations (3 meetings)
- EAC on Cells, Tissues and Organs Regulations (1 meeting)
- Scientific Advisory Panel (SAP) on Neuropathic Pain (1 meeting)
- SAP on Reprocessing of Medical Devices (1 meeting)
- SAP on Breast Implants (1 meeting)
- Federal/Provincial/Territorial (F/P/T) Group on Nutrition (4 meetings)
- Network on Healthy Eating (4 meetings)
- Veterinary Drugs Directorate Stakeholder Committee (2 meetings)
- Financial Models Reference Committee (1 meeting)
- Joint Steering Group for the Pilot Information Session for Patients and Consumers (see Section 2.3.3) (1 meeting)
- Natural Health Products Directorate Expert Advisory Council (2 meetings)
- Management Advisory Council for the Natural Health Products Directorate (4 meetings)
- Expert Advisory Committee (EAC) on Dietary Reference Intakes (2 meetings)
- Expert Advisory Panel (EAP) on Exclusive Breastfeeding (1 meeting)
- Food Guide Advisory Committee (2 meetings)

Advisory committees are made up of a wide range of members, including health professionals, industry representatives, academics, patient and consumer representatives, and government staff. Members are selected according to the purpose of each committee.

Participation in Advisory Committees

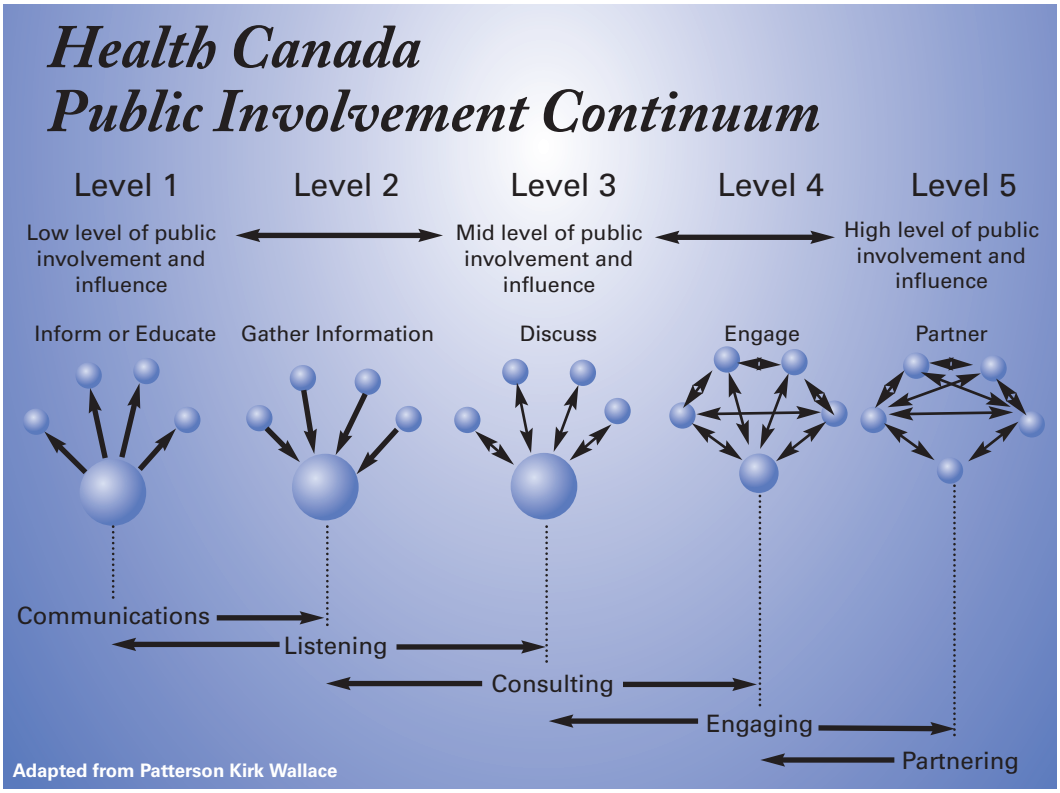


See Appendix D for more information on HPFB's advisory committees.

3.4 Outcomes

Bilateral meetings and advisory committees enabled the Branch to identify emerging issues and priorities; receive technical input into the development of programs, position papers and resource materials; and make more informed decisions. Participants benefited from increased co-operation and collaboration and the opportunity to contribute in a meaningful way to the Branch's decision-making processes.

Appendix A: Health Canada Public Involvement Continuum



Appendix B: Glossary of Public Involvement Methods

Advisory committee

Group of representatives from a particular community or with differing interests, who are selected by government bodies to advise, comment, review or make recommendations for action on any given issue. Terms of reference outline the responsibilities of advisory committees.

Bilateral meeting

Formal meeting usually between government and a stakeholder organization (public or private) mainly used to identify or clarify issues and increase the knowledge base on the issues. This category is part of a public involvement plan or strategy and excludes intermittent (meaning periodic or everyday) business meetings with stakeholders.

Canada Gazette Part 1

Posting of proposed regulatory changes in Part 1 of the *Canada Gazette*.

Dialogue

Structured and usually moderated process to discuss and deliberate on issues. This public involvement method enables participants with differing values and priorities to interact, exercise influence, and build a common understanding of the problems and opportunities. Types of dialogue include e-dialogues, appreciative inquiries, and deliberative dialogues.

Focus group

Structured process where specifically selected individuals are brought together to provide reactions to a specific topic, policy, project, or issue.

Mail-out for feedback

Distribution of feedback letters or information kits to stakeholders or interested parties to provide knowledge of a subject and seek input or comments (including e-mail notification).

Notice of Intent

Notice advising the public of Health Canada's intention to proceed with regulatory changes, initiatives or other actions.

Public meeting

Meeting open to stakeholders and the public where the government makes a formal presentation on a policy, project, or issue and the public is given the opportunity to react with questions and comments.

Round table

Meeting at which a group of people gather to discuss specific issues on which they have a common interest or expertise. The concept of a "round" table comes simply from the fact that no one is the "head" of the table.

Survey

Method of primary data collection based on communication with a representative sample of individuals using different information-gathering methods such as mail-out questionnaires, in-person or telephone interviews, and e-mail and Internet-based methods.

Technical consultation

Consultation in which selected participants with scientific or technical expertise are invited to provide input and feedback on the development of government guidelines, research programs, and so on (including expert working groups).

Web posting

Posting of an invitation to provide input on a question, issue, or document on the World Wide Web (including a call for briefs or proposals).

Workshop

Interactive meeting in which participants expect to be involved in group discussion on one or more theme areas. The intent is usually to identify problems and expectations or to recommend solutions.

Working group

Group of representatives from a particular community or with differing interests who are selected by government bodies to work together on a specific activity or project, towards a specific outcome. Working groups can work at strategic or operational levels.

Appendix C: Topics Addressed in Public Involvement Activities Conducted on a Per-Issue Basis

Face-to-Face Activities

Workshops (12)

Workshops that bring together representatives from diverse groups who share a common interest, but different perspectives, were held on the following issues:

- Summary Basis of Decision (SBD) documents (see Section 2.3.2)
- Animal health (Canadian Animal Health Institute)
- Implementation of *Q7A: Good Manufacturing Practices for Active Pharmaceutical Ingredients*
- Advisory committee orientation
- *HPFB Public Involvement Framework*
- Food allergen methodologies (third workshop)
- Identification of irradiated foods and ingredients in meals served by food service establishments
- New regulatory framework for human cells, tissues and organs for transplantation
- *Good Manufacturing Practices for Positron-Emitting Radiopharmaceuticals*
- Legislative renewal (meeting with key Veterinary Drugs Directorate stakeholders)
- Pilot Information Session for Patients and Consumers (see Section 2.3.3)
- Food Directorate Stakeholder Forum

Technical Consultations (2)

Technical consultations were conducted to obtain the technical expertise required on the following issues:

- *Good Manufacturing Practices for Positron-Emitting Radiopharmaceuticals*
- Regulatory requirements for human cells, tissues and organs for transplantation (first global consultation)

Focus Groups (3)

Focus group sessions were held to obtain feedback on the following topics:

- Manufacturing and compounding drug products in Canada
- Interactive nutrition label and quiz (qualitative research)
- Food fortification (see Section 2.3.1)

Public Meetings (2)

Public meetings were held to receive comments on the development of Canadian input into the elaboration of world-wide Codex standards for food safety, nutrition and quality.

Round Tables (2)

One round table was held with key Veterinary Drug Directorate stakeholders to discuss the issue of legislative renewal. Another was held to enable stakeholders to learn about and formulate a set of recommendations on West Nile virus testing of cell, tissue and organ donors

Other Types of Activities

Mail-Outs for Feedback (24)

HPFB issued mail-outs to solicit input from a wide audience on the following topics:

- Publication in *Canada Gazette* Part 1 of a proposal to remove Levonorgestrel from Schedule F of the *Food and Drug Regulations*

(when sold in concentrations of 0.75 mg per oral dosage unit)

- Publication in *Canada Gazette* Part 1 of a proposal to add Ferric Ferrocyanide to the *Food and Drug Regulations*
- Establishing maximum residue limits (MRLs) for Enrofloxacin and Eprinomectin
- *VICH GL38: Environmental Impact Assessements (EIAs) for Veterinary Medicinal Products (VMPs)-Phase II (Step 4)*
- *Guidance for Industry: Management of Regulatory Submissions*
- West Nile virus testing of cell, tissue and organ donors
- Pilot Information Session for Patients and Consumers (see Section 2.3.3)
- *HPFB Draft Policy on Voluntary Statement of Information for Public Involvement*
- Good guidance practices and good review practices initiatives
- Development of Canadian input into the elaboration of world-wide Codex standards for food safety, nutrition and quality
- Proposal to add Quinine to Schedule F of the *Food and Drug Regulations* (early consultation, Schedule 1431)
- Publication in *Canada Gazette* Part 1 of a proposal to add seven medicinal ingredients to Schedule F of the Food and Drug Regulations
- Amendments to the *Food and Drug Regulations* and the *Medical Devices Regulations*
- Publication in *Canada Gazette* Part 1 of a proposal to add 15 medicinal ingredients to Schedule F of the *Food and Drug Regulations*
- Draft recommendations from the subgroups within the Scientific Advisory Panel (SAP) on Hepatotoxicity on the hepatotoxicity of health products
- Industry consultations on *Draft Guidance for Industry: Issuance of Health Professional Communications and Health Product Consumer Updates by Market Authorization Holders*
- Draft variant Creutzfeldt-Jakob Disease (vCJD) directive
- *Draft Guidance for Industry: Private Label Medical Devices*
- Proposal to add Alefacept to Schedule F of the *Food and Drug Regulations* (early consultation, project 1445)
- Proposal to add seven new biologic and three pharmaceutical medicinal ingredients to Schedule F of the *Food and Drug Regulations* (early consultation, project 1434)
- *Draft Guide-0061: Risk Classification of Observations Made During Inspection of Blood Establishments*
- Importation of unapproved drugs for use in food-producing animals
- Development of Canadian input into the elaboration of world-wide Codex standards for food safety, nutrition and quality
- Annex to the *Good Manufacturing Practices for Positron-Emitting Radiopharmaceuticals*

Web Postings for Feedback (32)

HPFB posted web postings for feedback on the Health Canada web site on the following topics:

- *Draft Guidance for Industry: Use of Metabolite Data in Comparative Bioavailability Studies*
- *Draft Guidance for Industry: Bioequivalence Requirements-Comparative Bioavailability Studies Conducted in the Fed State*
- Publication in *Canada Gazette* Part 1 of a proposal to remove Levonorgestrel from Schedule F of the *Food and Drug Regulations* (when sold in concentrations of 0.75 mg per oral dosage unit)
- Publication in *Canada Gazette* Part 1 of a proposal to add Ferric Ferrocyanide to the *Food and Drug Regulations*
- *Draft (Step 2) International Conference on Harmonization (ICH) Guidance: E2E Pharmacovigilance Planning (E2E)*
- Establishing MRLs for Enrofloxacin and

Eprinomectin

- *VICH GL38: Environmental Impact Assessements (EIAs) for Veterinary Medicinal Products (VMPs)-Phase II (Step 4)*
- *Guidance for Industry: Management of Regulatory Submissions*
- West Nile virus testing of cell, tissue and organ donors
- Comment period for the *Draft Nutrition Recommendations for Canadians*
- *Guidance for Industry: Preparation of Veterinary New Drug Submissions*
- Pilot Information Session for Patients and Consumers (see Section 2.3.3)
- *HPFB Public Involvement Framework*
- Good guidance practices and good review practices initiatives
- *Draft Guidance for Industry: Drug Name Review-Look-alike/Sound-alike (LA/SA) Health Product Names and Draft Guidance for Industry: Marketed Health Product Name Assessment: Look-alike Sound-alike (LA/SA) Health Product Names*
- Development of Canadian input into the elaboration of world-wide Codex standards for food safety, nutrition and quality
- Proposal to add Quinine to Schedule F of the *Food and Drug Regulations* (early consultation, Schedule 1431)
- Publication in *Canada Gazette* Part I of a proposal to add seven medicinal ingredients to Schedule F of the *Food and Drug Regulations*
- Amendments to the *Food and Drug Regulations* and the *Medical Devices Regulations*
- Publication in *Canada Gazette* Part I of a proposal to add 15 medicinal ingredients to Schedule F of the *Food and Drug Regulations*
- Draft recommendations from the subgroups within the SAP on Hepatotoxicity on the hepatotoxicity of health products
- Regulatory requirements for human cells, tissues and organs for transplantation (first global consultation)
- Industry consultations on *Draft Guidance for Industry: Issuance of Health Professional Communications and Health Product Consumer Updates by Market Authorization Holders*
- *Draft Guidance for Industry: Private Label Medical Devices*
- Proposal to add Alefacept to Schedule F of the *Food and Drug Regulations* (early consultation, project 1445)
- Proposal to add seven new biologic and three pharmaceutical medicinal ingredients to Schedule F of the *Food and Drug Regulations* (early consultation, project 1434)
- *Draft Recall Policy*
- Amendment to the *Food and Drug Regulations*, Schedule 1390
- Animal Tissue Form (Veterinary Drugs Directorate)
- Importation of unapproved drugs for use in food-producing animals
- Notices of Submission for approval of plants with novel traits and novel feeds derived from these plants[6]
- Development of Canadian input into the elaboration of world-wide Codex standards for food safety, nutrition and quality

Companion Documents Not for Feedback (9)

HPFB provided companion documents for information only on the following topics. For each issue, additional public involvement activities were used to solicit feedback.

- Proposal to add seven medicinal ingredients to Schedule F of the *Food and Drugs Regulations* (early consultation)
- Proposal to remove Clobetasone Butyrate from Schedule F of the *Food and Drug Regulations* (early consultation)
- *Draft Guidance for Industry: Drug Name Review-Look-alike/Sound-alike (LA/SA) Health Product Names and Draft Guidance for Industry: Marketed*

[6] These Notices of Submission were posted as part of a pilot project managed by the Canadian Food Inspection Agency and Health Canada in co-operation with CropLife Canada.

Health Product Name Assessment: Look-alike Sound-alike (LA/SA) Health Product Names

- Development of Canadian input into the elaboration of world-wide Codex standards for food safety, nutrition and quality (two documents)
- Regulatory requirements for human cells, tissues and organs for transplantation (first global consultation)
- Notices of Submission for approval of plants with novel traits and novel feeds derived from these plants
- New regulatory framework for human cells, tissues and organs for transplantation
- Pilot Information Session for Patients and Consumers

Publications in Canada Gazette Part 1 (5)

HPFB published proposals in the *Canada Gazette* Part 1 to solicit feedback from interested parties on the following topics:

- Removal of Levonorgestrel from Schedule F of the *Food and Drug Regulations* (when sold in concentrations of 0.75 per oral dosage unit)
- Addition of Ferric Ferrocyanide to the *Food and Drug Regulations*
- Proposal to add seven medicinal ingredients to Schedule F of the *Food and Drug Regulations*
- Amendments to the *Food and Drug Regulations* and the *Medical Devices Regulations*
- Proposal to add 15 medicinal ingredients to Schedule F of the *Food and Drug Regulations*

Direct Mailings/Notices of Intent (9)

HPFB mailed information to interested parties on the following topics. For each issue, additional public involvement activities were used to solicit feedback:

- Removal of Clobetasone Butyrate from Schedule F of the *Food and Drug Regulations*
- Addition of seven medicinal ingredients to Schedule F of the *Food and Drug Regulations*
- Annex to the *Good Manufacturing Practices for Positron-Emitting Radiopharmaceuticals* (e-mail and Notice of Intent)
- Comment period for the *Draft Nutrition Recommendations for Canadians*
- *Draft Guidance for Industry: Drug Name Review-Look-alike/Sound-alike (LA/SA) Health Product Names and Draft Guidance for Industry: Marketed Health Product Name Assessment: Look-alike Sound-alike (LA/SA) Health Product Names*
- Development of Canadian input into the elaboration of world-wide Codex standards for food safety, nutrition and quality
- Draft vCJD directive
- Establishing MRLs for Enrofloxacin and Eprinomectin in edible tissues of food-producing animals and milk

Survey (1)

A survey was provided to a representative group to gather specific feedback for use in determining information and support requirements for patients and consumers and developing a pilot orientation session for advisory committee members (see Section 2.3.3).

Phone Interview (1)

HPFB conducted a phone interview to obtain feedback on the *Draft HPFB Strategic Framework on International Regulatory Co-operation.*

Appendix D: HPFB Committees

In addition to two branch-wide committees, HPFB manages and consults with a number of established committees to provide advice and, in some cases, to act as sounding boards to the Branch and to other Health Canada officials as they carry out their work. These committees are made up of a wide range of members, including health professionals, industry representatives, academics, patient and consumer representatives, and government staff. Members are selected according to the purpose of each committee.

The following list represents those committees with which HPFB met during the 2004-2005 period:

Branch-Wide Committees

Advisory Committee on Management

The Advisory Committee on Management (ACM) is a standing committee that provides feedback, recommendations, and advice on management issues relevant to HPFB. The Committee provides advice on areas such as cost recovery, performance, continuous quality improvement and other management initiatives. The 19-member committee includes representatives from industry, health professionals, academia, government, and public and consumer organizations.

Public Advisory Committee

The Public Advisory Committee (PAC) is an innovative forum that provides advice from the public's perspective on HPFB issues and initiatives. The PAC's 16 members are individual citizens who do not represent any organizations. The PAC was established in response to public desire for more information about health protection issues and the need for greater public involvement in the development of policies and programs designed to protect their health and safety. The Committee has provided HPFB with advice on Branch planning, legislative renewal, advertising of health products, dispute resolution, communicating drug safety information, biotechnology, and risk communication.

Scientific/Expert Advisory Committees

Scientific Advisory Committees (SACs) and Expert Advisory Committees (EACs) are standing committees that provide ongoing medical, technical and scientific advice and recommendations on regulatory issues for drugs and medical devices in specific therapeutic areas or classes. Committee members are chosen through a formal nomination process involving a wide range of stakeholders.

- **SAC on HIV Therapies:** This standing committee provides ongoing and timely medical, scientific, and clinical advice on current and emerging issues related to HIV therapies, vaccines, and pre- and post-market HIV/AIDS-related products.
- **SAC on Bioavailability and Bioequivalence:** This standing committee provides ongoing and timely medical, scientific, and clinical advice on issues related to work on the bioavailability and bioequivalence of drugs.
- **SAC on Medical Devices Used in the Cardiovascular System:** This standing committee provides ongoing advice on matters related to medical devices used in the cardiovascular system.
- **EAC on Blood Regulations:** This standing committee provides the Biologics and Genetic Therapies Division with timely advice on medical and scientific issues relevant to deferral responsibilities within the national blood system.
- **EAC on Cells, Tissues and Organs (CTO) Regulations:** This committee provides the Biologics and Genetic Therapies Directorate with timely advice regarding the development and implementation of the proposed CTO regulations.
- **Food Guide Advisory Committee**: This committee provides the Office of Nutrition Policy and Promotion with advice and guidance related to the revision of Canada's Food Guide to Healthy Eating and supporting materials.

- **EAC on Dietary Reference Intakes:** This committee provides the Office of Nutrition Policy and Promotion with timely advice and recommendations on how best to address issues related to implementation through the application of the Dietary Reference Intakes.

Scientific/Expert Advisory Panels

Scientific Advisory Panels (SAPs) provide medical, technical, and scientific advice and recommendations on a variety of issues, including those related to the safety and efficacy of some of the products regulated by the Health Canada. Panel members are appointed by Health Canada.

- **Expert Advisory Panel on Exclusive Breastfeeding:** This committee provided the Office of Nutrition Policy and Promotion with advice on the development of a statement regarding the duration of exclusive breastfeeding.
- **SAP on Neuropathic Pain:** This panel provides ongoing medical, technical and scientific advice and recommendations on regulatory issues for drugs used for treatment of neuropathic pain and related conditions.
- **SAP on Reprocessing of Medical Devices:** This panel provides technical and scientific advice on current and emerging issues related to the reprocessing of medical devices.
- **SAP on Breast Implants:** This panel provides medical, technical and scientific advice and recommendations on regulatory issues for silicone gel-filled breast implants.

Federal/Provincial/Territorial Committees

Federal/Provincial/Territorial (F/P/T) committees encourage collaboration between governments in addressing particular issues.

- **F/P/T Group on Nutrition:** This standing committee provides leadership in stimulating and accelerating actions to achieve nutritional well being for all Canadians.

Other Committees and Working Groups

- **Network on Healthy Eating:** This standing committee enhances collaboration, co-operation, and coordination of efforts to support healthy eating and nutrition in Canada.
- **Veterinary Drugs Directorate Stakeholder Committee:** This committee provides a forum for obtaining input from the stakeholder community on key issues that fall under the purview of the Veterinary Drugs Directorate.
- **Financial Models Reference Committee:** This committee provides advice on cost, fee and revenue allocation models to support changes to HPFB's regulatory fee regulations.
- **Joint Steering Group for the Pilot Information Session for Patients and Consumers:** This steering group was formed to provide advice and guidance to OCAPI on the development and delivery of the pilot information session for patients and consumers. Members participated in the review and validation of content and delivery options for the pilot session (see Section 2.3.3).
- **Natural Health Products Directorate Expert Advisory Council:** This council provides expert advice to the Natural Health Products Directorate on issues relating to the safety, quality and efficacy of natural health products.
- **Management Advisory Committee for the Natural Health Products Directorate:** This committee discuses and resolves issues pertaining to the management and administration of natural health products.

Appendix E: For More Information

To obtain more information or to provide your feedback on this report, please contact the Office of Consumer and Public Involvement at the following address:

Office of Consumer and Public Involvement

Suite 513
Holland Cross, Tower A
11 Holland Ave
Address Locator: 3005A
Ottawa ON K1A 0K9
Fax: (613) 954-8637
E-mail: ocapi-bpcp@hc-sc.gc.ca

Appendix F: Evaluation Questionnaire

The following questionnaire will be used by the Office of Consumer and Public Involvement (OCAPI) to evaluate the usefulness and quality of the *HPFB Public Involvement Annual Performance Report*. This report covers events that the Branch has conducted between April 2004 and March 2005. Your suggestions and recommendations will be used to improve future annual reports.

Please indicate the category that best applies to you:

- ☐ Academia
- ☐ Community or Consumer Group
- ☐ General Public/Citizen
- ☐ Government
- ☐ Health Professional
- ☐ Industry
- ☐ Patient Group
- ☐ Other: _____

1) I am more aware of the Branch's public involvement activities because of this report.

- ☐ Strongly Agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly Disagree
- ☐ Don't Know

2) This report provides me with useful information on the Branch's public involvement activities.

- ☐ Strongly Agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly Disagree
- ☐ Don't Know

3) The information is presented clearly.

- ☐ Strongly Agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly Disagree
- ☐ Don't Know

4) The information is meaningful to me.

- ☐ Strongly Agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly Disagree
- ☐ Don't Know

5) It is clear how the Branch uses information received from public involvement activities.

- ☐ Strongly Agree
- ☐ Agree
- ☐ Disagree
- ☐ Strongly Disagree
- ☐ Don't Know

6) What information in this report is most valuable to you?

_____

_____

_____

_____

_____

_____

7) What information is not useful or relevant to you?

8) Is there any information that could be presented differently?

9) What additional information regarding public involvement activities do you feel should be included in this report?

10) Understanding that measuring the value of public involvement activities is difficult, are there other indicators which you think would be valuable?

11) What other changes would you recommend to improve on this report?

12) General Comments:

13) We are currently posting this report on the OCAPI web site and the HPFB web site, and distributing it via e-mail using a list of Branch stakeholders. Can you suggest other ways in which we could distribute this report?

Please mail or fax your completed questionnaire to the following address:

Office of Consumer and Public Involvement
Suite 513
Holland Cross, Tower A
11 Holland Ave
Address Locator: 3005A
Ottawa, ON
K1A 0K9
Fax: (613)954-8637

Thank you for your feedback.