Health Products and Food Branch

# 2007 Review of Regulated Products: Policy on Public Input

Canada

**Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.** We assess the safety of drugs and many consumer products, help improve the safety of food, and provide information to Canadians to help them make healthy decisions. We provide health services to First Nations people and to Inuit communities. We work with the provinces to ensure our health care system serves the needs of Canadians.

Health Products and Food Branch Review of Regulated Products: Policy on Public Input is available on Internet at the following address:
http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/public-rev-exam/index_e.html

Également disponible en français :
http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/public-rev-exam/index_f.html

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# Table of Contents

## Preamble

This policy is part of the Health Products and Food Branch's commitment to improved transparency, openness, and accountability made in its *2004–07 Strategic Plan: Serving Canadians—Now and Into the Future* and further developed in the Branch's Public Involvement Framework. The policy sets out a predictable process to follow when the Branch identifies situations where its decision making would benefit from public input. Regardless of the process followed, the Branch has legislative responsibility for the product review and always retains the decision-making authority.

## Statement

Sharing information and including a range of perspectives in the decision-making process enhances the quality, credibility, and accountability of the decisions the Health Products and Food Branch makes about a regulated product, and encourages public trust in its decision making.

Drawing from Government of Canada policies and commitments, including the Health Products and Food Branch's Public Involvement Framework, the Health Products and Food Branch is committed to the following:

- **Independence and accountability in decision making.** The Health Products and Food Branch makes decisions on a regulated product objectively, independently, and without bias, according to its legislated mandate under the *Food and Drugs Act* and regulations.

- **Making decisions in the public interest.** Health Canada's mission is to help "the people of Canada maintain and improve their health." Regulatory decisions in the public interest require Health Canada to identify and assess the safety and effectiveness of a regulated product to determine the level of acceptable risk weighed against the product's benefits.

- **Openness and inclusiveness in our review process.** The Health Products and Food Branch recognizes that public input from a variety of sources can lead to more informed analysis of the safety and effectiveness of a regulated product.

- **Transparency.** To allow for informed public input while also respecting the privacy of individuals and confidential business information, the Health Products and Food Branch will provide the public with sufficient information on the review of a regulated product and the issues under consideration.

- **Timeliness.** The Health Products and Food Branch will inform the public of opportunities to provide input as soon as possible and will always endeavour to give the public enough time to prepare.

- **A flexible approach.** The Health Products and Food Branch will use a variety of approaches to gather public input when it reviews a regulated product, depending on the issue under consideration and the nature of the input it requires.

# Section 1: Authority for and scope of the policy

**Authority for the policy**

1.1 For the purposes of carrying out Health Canada's duties under the *Food and Drugs Act*, the Minister or the Minister's delegate may seek and consider public input in its regulatory decision making.

The relevant regulatory provisions governing the review of food are in the *Food and Drugs Regulations* B.16.002, B.25.046, B.25.048, B25.060, B.26.005, and B.28.002. The relevant regulatory provisions governing the review of new drug submissions by the Department are in the *Food and Drugs Regulations* C.08.002 (1), C.08.004 (1), C.08.004 (2), and C.08.004 (3).

The provisions of the *Access to Information Act*, the *Privacy Act*, and the *Official Languages Act* are also relevant to this policy.

**Scope of the policy**

1.2 This policy applies to all review directorates of Health Canada's Health Products and Food Branch.

## Section 2: Opportunities for public input

**Decision to seek public input**

2.1 To inform its decision making, the Health Products and Food Branch may seek public input at any time when it is reviewing a regulated product or class of products. In this policy, the term "public input" means input from external individuals and organizations other than the sponsors and manufacturers that are researching, producing, or marketing the regulated product.

**Notice to sponsor of the public input process**

2.2 When it decides to seek public input on a regulated product, the Health Products and Food Branch will inform the sponsor or manufacturer in writing. The letter stating the intention to include a public input process in the product review will include reasons for this decision, and will identify the type of public input process the Branch will use and time frames.

**Sponsor participation in the public input process**

2.3 The participation of a sponsor or manufacturer of a regulated product in the public input process will depend on the type of process used. Procedural fairness requirements will be observed.

**Reasons to seek public input**

2.4 The Assistant Deputy Minister or delegate may seek public input related to the safety and effectiveness of a regulated product when the Health Products and Food Branch

a. requires professional or scientific advice to supplement internal expertise in analyzing data on the safety, effectiveness, quality, or safe use of a regulated product;

b. requires advice, given the lack of scientific certainty or conclusive data on the safety, effectiveness, or safe use of a regulated product;

c. requires advice from stakeholders with knowledge and experience in different areas, particularly those who use or might use the regulated product, to broaden the information available to make an informed evaluation of the risk and

benefit associated with a product and how the risk may be mitigated or eliminated; and

d. recognizes existing or potential public concern about the safety, effectiveness, quality, or safe use of a regulated product and believes public input will provide the Branch with a better understanding of those concerns.

**Factors affecting the public input process**

2.5 The Health Products and Food Branch may consider the following factors in determining the nature and extent of the public input process:

a. the nature, scope, and significance of the issue to be considered and its relevance to the Branch's regulatory and legislative mandate;

b. the size, health status, or characteristics of the population affected by the outcome of the review;

c. the level of public concern about a regulated product;

d. the time and resources available;

e. whether the Branch or another regulatory body sought public input on a similar regulated product in the last two years; and

f. procedural fairness and the protection of confidential business information.

**Ways to receive public input**

2.6 To receive public input on the safety and effectiveness of a regulated product, the Health Products and Food Branch may

a. ask an advisory body to answer specific questions about a regulated product, which could include asking it to consider input from the public or specific individuals or groups before answering those questions;

b. meet with anyone who has information that would help with the product review;

c. invite written remarks from the public or specific individuals or groups;

d. organize workshops, focus groups, or other types of in-person or electronic consultations;

e. invite the public or specific individuals or groups to make presentations at a public forum;

f. conduct public opinion research, surveys, media analysis, or other activities;

g. ask a third party to organize a consultation and report back to the Branch; or

h. undertake any other public input activity to gather information that would help it make an informed decision.

**Advisory bodies: conflict of interest**

2.7 A person with a direct financial interest in the outcome of a review of a regulated product, as defined in the Health Product and Food Branch's *Guidance on Advisory Bodies*, may not be a member of an advisory body whose mandate is solely to provide advice on specific matters relating to the review. In this situation, the Branch considers direct financial interest in a product review to be a conflict of interest.

2.8 A person with a direct financial interest in the outcome of a review of a regulated product may be a member of an advisory body whose broader mandate encompasses matters of policy, management, or program development. However, such a member may not participate in any discussion, formulation of advice, or recommendations by the advisory body to the Branch relating to the review.

**Advisory bodies: affiliations and interests**

2.9 The Health Products and Food Branch recognizes that a person with affiliations and interests that do not constitute a direct financial interest in the outcome of a product review, as described in its *Guidance on Advisory Bodies,* may have valuable input to

offer based on his or her expertise or experience. Persons with such affiliations and interests may be considered for advisory body membership.

2.10 The Health Products and Food Branch strives for a range of affiliations and interests in an advisory body with a view to ensuring a diversity of perspectives, and always taking into account the credibility of the advice the advisory body will give the Branch.

**Advisory bodies: transparency of membership**

2.11 The Health Products and Food Branch will ensure that standards of transparency for the membership of its advisory bodies are met, as set out in its *Guidance on Advisory Bodies.*

**Application of the *Policy on Voluntary Statement of Information for Public Involvement***

2.12 When it seeks public input other than from an advisory body, the Health Products and Food Branch will encourage all participants in the public input process to voluntarily provide basic information about themselves and/or the organizations they represent. The Branch's *Policy on Voluntary Statement of Information for Public Involvement* applies in this situation and can be found at *www.hc-sc.gc.ca/ahc-asc/pubs/cons-pub/vsi_pvi_intro_e.html*.

**Official language of choice**

2.13 Depending on the process the Health Products and Food Branch uses to receive public input, members of the public may provide information in writing or orally in the official language of their choice.

# Section 3: Types of public input

**Various types of input**

3.1 When the Health Products and Food Branch decides to seek information from the public on the safety and effectiveness of a regulated product, it may consider various types of input, including the following:

a. scientific research that others can replicate independently;

b. professional and personal knowledge and experience; and

c. information about values, habits, and traditions that may influence the safe use and effectiveness of a product.

## Section 4: The release of information about a regulated product

**Informed participation**

4.1 The Health Products and Food Branch will provide the public with information on the regulated product under review that is relevant to the public input process. The purpose of providing this information is to enable informed public participation in the decision-making process, which in turn can enhance the quality of regulatory decisions.

**Courtesy notice to sponsor or manufacturer**

4.2 The Health Products and Food Branch will, as a courtesy, provide the sponsor or manufacturer of the regulated product under review with a copy of all the information before releasing it to the public.

**Consent required**

4.3 The Health Products and Food Branch will seek the sponsor or manufacturer's consent if it intends to publish the following information about a regulated product:

a. the fact that an application for market authorization of a regulated product has been submitted to the Branch;

b. Periodic Safety Update Reports issued under the Canadian Adverse Drug Reaction Monitoring Program;

c. summary safety reports;

d. relevant clinical and non-clinical data;

e. a summary of submission data, such as a briefing book; and

f. information received from other areas of the Department, a Canadian institution, foreign government or international organization, with confidential business information removed and subject to the consent of appropriate regulatory authorities.

**Consent not required**

4.4 Information that the Health Products and Food Branch may publish without the consent of the sponsor or manufacturer of the regulated product includes the following:

a. information that originates with the Government of Canada, with confidential business information removed;

b. information that is in the public domain, for example, information accessible on the Internet or that was made public as part of a similar process in another jurisdiction;

c. information that has been previously released in response to an Access to Information request;

d. extracts of information that has been collected in the Canadian Adverse Drug Reaction Monitoring Program; and

e. the official Canadian Product Monograph.

**Consent at any time**

4.5 At any time during the review process, the sponsor or manufacturer may proactively consent to the public release of all or parts of the information it has submitted to the Health Products and Food Branch as part of the review process.

**Considerations**

4.6 Before the Health Products and Food Branch makes public any information it has concerning a regulated product, it will consider the following:

a. the privacy of any personal information that is protected by legislation. For example, privacy legislation prohibits providing information, such as a name and address, that would identify a person who participated in a clinical trial, or who reported an adverse reaction to a regulated product;

b. the confidentiality of the information—whether it is confidential business information or in the public domain;

c. any commitments Canada has made by signing an international trade agreement. For example, international agreements protect undisclosed test data that has been submitted as a condition of seeking authorization for a pharmaceutical product that uses new chemical entities; and

d. the need arising from public health and safety considerations to communicate a product's risk and benefit information.

**Accessible information**

4.7 The Health Products and Food Branch will encourage the sponsor or manufacturer to provide product information in a format that is accessible to the participants of the public input process. In particular, the Branch will encourage sponsors to make information available in both official languages.

**Internet access to documents**

4.8 The Health Products and Food Branch will post on the Internet the product information that it has made public under paragraph 4.1.

## Section 5: Public notice

**Initial public notice**

5.1 When the Health Products and Food Branch decides that the review of a regulated product requires public input other than advice from an advisory body, it will issue a notice and post it on the Health Canada and Government of Canada Web sites. The notice will

a. include reasons for this decision;

b. identify the type of public input process the Branch will use;

c. if a meeting is planned, provide information about whether the meeting, or portions of the meeting, will be open to observers; and

d. set the deadline for the public to provide input.

**Subsequent public notice**

5.2 When the Health Products and Food Branch has clarified details of the public input process, it will post an additional notice on the Health Canada and Government of Canada Web sites on the nature and scope of the input it seeks.

**Timing**

5.3 The Health Products and Food Branch will inform the public of opportunities to provide input as soon as possible. However, target times for the completion of reviews set by the Branch, and the nature, scope, significance, and urgency of the issue may affect the amount of advance notice the Branch can provide to the public.

# Section 6: The consideration of public input

**Information on product safety and effectiveness**

6.1 Before making decisions based on its review of a regulated product, the Health Products and Food Branch will consider information it has received from the public input process. It will limit this consideration to information that pertains to the safety and effectiveness of the product.

**Reliability and relevance of information**

6.2 Before using information received from public input, the Health Products and Food Branch will assess its reliability and relevance using standardized measures.

**Factors affecting reliability and relevance**

6.3 In determining the reliability and relevance of the information, the Branch will consider the following factors:

a. the degree to which the information pertains to the safety and effectiveness of a regulated product;

b. whether a previous peer review or juried evaluation of the information has taken place, or whether the information is consistent with the findings of any peer review or juried evaluation that has taken place in Canada or elsewhere;

c. whether this information contributes to a more complete picture of the safe and effective real-world use of a regulated product than can be provided by the Branch's usual sources of evidence; and

d. the degree to which the information is based on reliable and credible expertise or experience, and the extent to which this might be affected by the nature of the affiliations and interests the person or organization providing the information has.

**Role of public input information**

6.4 The Health Products and Food Branch must make its decision on the safety and effectiveness of a regulated product according to the requirements of the *Food and Drugs Act* and its regulations. Scientific data forms the primary basis of any product review.

Public input, which can include scientific as well as other types of evidence, can bring additional perspectives relevant to an evaluation of safety and effectiveness by

a. identifying gaps or more suitable methods in scientific research;

b. contributing new information on the safety and effectiveness of a regulated product in real-world use;

c. identifying, assessing, and balancing the risks and benefits of a regulated product, including the nature and degree of acceptable risk; or

d. identifying strategies to mitigate risk when it cannot be eliminated, including advice on what and how information on a regulated product should be made available to the public.

## Section 7: Reporting

**Report on the public input received**

7.1 The Health Products and Food Branch will make public on the Health Canada Web site a report on the public input received. The report will include the type of process used, the objectives, and an overview of the input.

## Glossary

**Advisory body** Individuals appointed by the Health Products and Food Branch, based on their expertise and experience, to provide advice to the Branch according to their mandate and terms of reference.

**Confidential business information** Financially valuable information belonging to a business that is normally kept secret by that business. It can include trade secrets, or financial, commercial, scientific, or technical information, the disclosure of which could result in financial loss or gain to, or prejudice the competitive position of, a third party.

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

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

**Industry** A subset of stakeholders comprising for-profit organizations involved in research, wholesale, distribution, or manufacturing.

**Manufacturer** A person, association, or partnership that sells food or a drug under its own name, design, or word mark, trade name, or other name, word, or mark that it controls.

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

**Public** In this policy, everyone external to government except the sponsor or the manufacturer of the regulated product or class of products under review.

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| Public forum | An open meeting where the public, including academics, consumers, health professionals, industry representatives, patients, and any other interested parties, make presentations. Anyone may observe the meeting. Presenters may state their views in person, online, or by fax or mail; there is no formal discussion with or among participants. |
| Regulated product | Pharmaceuticals, medical devices, biologics and genetic therapies, natural health products, veterinary drugs, food products, and classes of products. |
| Safety | The relative risk of harm. The determination of safety includes defining the type, level, and scope of adverse events, reactions, and hazards, and balancing this against the benefits of a product in order to develop an appropriate risk-benefit assessment. |
| Sponsor | For the purpose of this policy, the term sponsor refers to either an applicant for market authorization of a regulated product or a holder of a licence to sell a regulated product in Canada. |
| Stakeholder | An individual, group, or organization that is affected by or interested in an issue, decision, or action by the Branch including a regulated product or class of products. |