2007

Guidance for the Health Products and Food Branch

Review of Regulated Products: Policy on Public Input

Guidance

Notice of the Public Input Process
Information Supporting the Public Input Process
Reporting on Public Input
Public Forums

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.

These Guidance documents are 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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About this Document

The Office of Consumer and Public Involvement of the Health Products and Food Branch has developed a policy—*Health Products and Food Branch Review of Regulated Products: Policy on Public Input*. The Policy outlines a predictable process to follow when the Branch identifies situations where its decision making would benefit from public input.

Containing best practices consistent with the Policy, the following set of guidance documents is meant for Branch employees, advisors, and stakeholders. The guidance provides staff with flexibility in planning and delivering public input activities that are appropriate to the issue under consideration and the nature of the input required. It provides stakeholders with predictability in what they can expect from the Branch when it decides to seek public input.

These guidance documents should be read in conjunction with the Policy and specifically relate to

- Notice of the Public Input Process
- Information Supporting the Public Input Process
- Reporting on Public Input
- Public Forums

The policy and guidance continue to be living documents. Should you have feedback you would like to share, based on your experience in using these tools, please contact:

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Guidance on Notice of the Public Input Process

The following *Guidance on Notice of the Public Input Process* should be read in conjunction with Section 5 of the Policy, "Public notice," which requires the Branch to provide notice to the public when it has decided to seek public input in a product review.

Timing of the public notice

1.1 Within the target times it sets to complete reviews, the Health Products and Food Branch should make every effort to respect the following notice period:

Six weeks' notice for public input. Preparation time is important to ensure informed and relevant public input. If the Branch decides to seek input from the public on a regulated product, it will notify the public at least six weeks before the public input deadline. If the Branch cannot give six weeks' notice, it will make every effort to facilitate public input within reduced time frames.

Additional information in the public notice

2.1 Paragraph 5.1 of the Policy requires the Branch to notify the public of the type of public input process it will use; whether a meeting, if planned, is open to observers; and the deadlines for public input. In addition to these requirements, the Health Products and Food Branch may also include the following information in the notice:

a. the scope of public input it seeks, for example, the extent of participation and type of process;

b. the opportunities for the public to provide input;

c. how the Branch will use the information it receives from the public in its decision-making process;

d. a Web site address with more information on the regulated product under review and the public input process; and

e. the name and contact information of the Branch official coordinating the public input process.

Other forms of public notice

3.1 In addition to the notice published on the Health Canada Web site required by paragraph 5.1 of the Policy, the Health Products and

Food Branch may also

a. send a letter or e-mail to specific individuals or groups;

b. issue a notice for distribution in the media, for example, in newspapers or on radio and television;

c. issue a notice for distribution at contact points, for example, at family physician offices or pharmacies;

d. post or distribute a notice at public events; or

e. use other appropriate ways to notify the public, for example, partner with a stakeholder organization to reach a target population.

Guidance on Information Supporting the Public Input Process

The following *Guidance on Information Supporting the Public Input Process* should be read in conjunction with Section 4 of the Policy, "The release of information about a regulated product," which documents how the Health Products and Food Branch will manage information during a public input process as part of a product review.

Listing of information the Health Products and Food Branch has made public

1.1 Paragraph 4.6 of the Policy describes the Branch's considerations in making any information public. To increase transparency and public access to information about a regulated product under review, the Health Products and Food Branch will post on the Internet a listing of the regulated product information it has made public in support of a public input process. The listing will be separated into appropriate categories. For example, information about a regulated product might fall into categories such as "clinical trials," "studies," and "theoretical papers."

Courtesy information regarding the publication of product information

2.1 Paragraph 4.3 of the Policy describes the information for which the Health Products and Food Branch requires the consent of sponsors or manufacturers in order to make it available to the public. When consent is not required, the Branch will, as a courtesy, inform the sponsor or manufacturer at least 48 hours before the publication of information about the product and provide the sponsor or manufacturer with a summary of the information.

Guidance on Reporting on Public Input

The following *Guidance on Reporting on Public Input* should be read in conjunction with Section 7 of the Policy, "Reporting," which requires the Branch to make public a report on the public input received.

Summary of public input

1.1 The Health Products and Food Branch will prepare, or have a third party prepare, a summary report of public input received through a public involvement activity. In addition to the requirements of paragraph 7.1 of the Policy, the summary will include an overview of stakeholder participation. The *Guidance on Advisory Bodies* and the *Guidance on Public Forums* provide further guidance on reporting practices.

Availability of the public input report

2.1 The Health Products and Food Branch will post the public input report on the Health Canada Web site. It will also provide a copy to participants and to advisory bodies with a related mandate.

Advance copy for sponsor or manufacturer

3.1 For information-sharing purposes only, the Health Products and Food Branch will provide a final public input report to the sponsor or manufacturer 48 hours before its public release.

Opportunity to respond to public input issues

4.1 When the Health Products and Food Branch has sought public input in the review of a regulated product, it will invite the sponsor or manufacturer to respond to any issues that arose through the public input process before it makes a decision.

Reporting on how public input is considered

5.1 When the Health Products and Food Branch has sought public input in the review of a regulated product, it will report on how it considered the input at the time of its decision. The report will include

a. the reason for seeking public input;

b. the type of public input process the Branch used;

c. an overview of the input the Branch received from the

public; and

d. how the Branch considered the public input in its decision.

Reporting standards

6.1 Reports will be available in both official languages.

6.2 Reports posted online will comply with the Treasury Board's *Common Look and Feel Standards for the Internet*, available at www.tbs-sct.gc.ca/clf-nsi/index_e.asp , and Health Canada's *Guidelines for Presentation of Reports and Publications*, and *Guidelines for Presentation of Public Involvement Activities and Consultations*.

Guidance on Public Forums

The following *Guidance on Public Forums* should be read in conjunction with Section 2 of the Policy, "Opportunities for public input," which describes when and how the Health Products and Food Branch may seek public input as part of a product review.

Definition

A "public forum" is an open meeting where the public, including academics, consumers, health professionals, industry representatives, patients, and any other interested party, 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. A public forum can be held independently, or in conjunction with an advisory body meeting or other public input activities.

Reasons to hold a forum

1.1 When the Health Products and Food Branch has decided to seek public input to make an informed decision on its review of a regulated product, it has a variety of mechanisms available to gather that input. The Branch may specifically choose to hold a public forum to

a. allow a broad range of members of the public to provide information about the safety and effectiveness of a regulated product;

b. increase its understanding of public perspectives when there is controversy in the public domain concerning the safety or effectiveness of a regulated product; and

c. increase public awareness and understanding of the following: the risks, benefits, and other issues related to the safety and effectiveness of a regulated product; the diversity of stakeholder perspectives on the issues; and the process the Branch follows in reviewing a regulated product.

Focus of a forum

2.1 The Health Products and Food Branch determines the topic of a public forum and the specific questions on the safety and effectiveness of a regulated product for the public to address.

Organization

3.1 The Health Products and Food Branch determines the organization of the public forum including the following:

a. design and format,

b. agenda,

c. location,

d. room set up,

e. scheduling,

f. duration,

g. who will give an in-person presentation and in what order,

h. time available for each in-person presentation,

i. role of the sponsor or manufacturer,

j. systems to protect confidential business information,

k. who will facilitate, and

l. any other matters that concern the organization of the public forum.

Consultation

4.1 Before determining the organization of a public forum, the Health Products and Food Branch will consult with the chair of any advisory body whose mandate relates to the topic of the public forum, and the sponsor or manufacturer of the regulated product under review. It may also consult with any other stakeholders.

Public notice

5.1 The Health Products and Food Branch will follow Section 5 of the Policy, which requires the Branch to provide notice to the public, and the *Guidance on Notice of the Public Input Process* when it has decided to seek public input in a product review through a public forum.

Request to present

6.1 Members of the public who wish to make a presentation must submit a request to the Health Products and Food Branch and provide their input according to the instructions in the public notice.

Accommodation measures

7.1 If participants require accommodation measures, such as technical aids or accessibility requirements, to make an in-person presentation, they should inform the Health Products and Food Branch as soon as possible and no later than 14 days before the event.

Late material

8.1 The Health Products and Food Branch cannot guarantee that it will consider public input that it receives after the deadline provided in the notice.

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

9.1 The Health Products and Food Branch will encourage all participants who wish to make a presentation to a public forum, whether in person, online, by fax, or by mail, 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*.

Factors for selecting public presentations

10.1 After the deadline for receiving requests to present in person, the Health Products and Food Branch will assess how many requests it received. If possible, the Branch will provide everyone who met the deadline with a presentation time. If not, the Branch will decide on the presenters by giving priority to

a. presentations that provide information directly related to the specific topic or topics of the forum;

b. presenters with research results or other quantitative information;

c. presenters who represent the views of an organization or

association;

d. presenters with a unique perspective or experience;

e. a range of presenters with different perspectives;

f. presenters who may have difficulty providing comments in writing; and

g. presenters who are Canadian citizens or permanent residents.

Factors affecting the amount of time for a presentation

11.1 The amount of time for an in-person presentation will be decided by the Health Products and Food Branch and will depend on

a. the number of presentations;

b. the nature, relevance, and reliability of each presentation; and

c. the amount of time for the public forum.

Time allotment: public

12.1 In general, the amount of time allotted for public presentations will be as follows:

a. a personal experience—3 to 5 minutes;

b. information from an organization or association—5 to 8 minutes; and

c. research results or quantitative information—8 to 10 minutes.

Time allotment: sponsor or manufacturer

13.1 Sponsors or manufacturers will have an opportunity to provide information on their regulated products at the public forum. In addition, all participants in a public forum benefit from hearing the supporting information that a sponsor or manufacturer has submitted to the Health Products and Food Branch. The amount of time a sponsor or manufacturer will have to present information and research results on the safety, effectiveness, quality, or safe use of a regulated product will be between 30 to 60 minutes. If the manufacturer is presenting information on several products, its presentations in total will not exceed 90 minutes.

Time allotment: Health Products and Food Branch

14.1 The amount of time the Health Products and Food Branch will have to present information at the public forum will be 30 to 60 minutes.

Order of public presentations

15.1 The Health Products and Food Branch will decide on the order of public presentations at the public forum based on a variety of factors, including

a. a balance and flow of presentations; and

b. a presenter's special circumstances, such as a health condition.

15.2 After considering the factors for selecting public presentations, the Health Products and Food Branch may randomly determine the final list of presenters.

List of public presentations

16.1 The Health Products and Food Branch will finalize the list of public presentations at least seven days before the public forum. To protect presenters from interference or influence before their presentation, the Branch will not disclose the names of presenters in advance of the forum; instead, it will assign each presenter a number. It will provide presenters with the time and number of their presentation.

Availability for questions

17.1 The Health Products and Food Branch will ask presenters to be available to answer clarification questions following their presentations.

Substitutions

18.1 If a presenter cannot appear in person, a substitute will be allowed only if the presenter represents an organization. In this case, another representative of the organization may speak.

The agenda for the forum

19.1 The agenda will include the schedule for the forum and the list of presentations. The Health Products and Food Branch will post the agenda on its Web site at least seven days before the public forum.

Appointment of a facilitator

20.1 The Health Products and Food Branch may appoint a facilitator to run the public forum.

Role of the facilitator

21.1 The facilitator will help to ensure that the forum proceeds in an efficient and focused manner. For example, the facilitator will ensure that all presenters have their allotted opportunity to speak. He or she will also stop presenters if, despite receiving a warning, they

a. exceed their time limit;

b. are not on topic and have not refocused their presentation to the topic; or

c. are making disrespectful, defamatory, or libellous statements.

Role of an advisory body in a public forum

22.1 If the Health Products and Food Branch has asked an advisory body to consider the input from a public forum before writing its report, the chair and members of the advisory body will attend the public forum.

22.2 The Health Products and Food Branch will introduce members of the advisory body at the start of the forum and make public a summary of their expertise, affiliations, and interests.

22.3 At a public forum, members of the advisory body may ask a presenter questions to clarify or expand on what he or she has said.

Role of sponsor or manufacturer

23.1 When sponsors or manufacturers make presentations at a public forum, they must provide the Health Products and Food Branch with a list of their presentation team at least 30 days before the public forum. A member of the sponsor's or manufacturer's presentation team may speak at the forum only as part of that team.

Health Products and Food Branch liaison with sponsor or manufacturer

24.1 The Health Products and Food Branch will appoint an official to act as the point of contact for the sponsor or manufacturer for any issues arising over the course of the public forum that, in the

Branch's view, relate to or affect the sponsor's or manufacturer's right to a fair procedure.

Role of the media

25.1 Members of the media are welcome to attend a public forum.

Health Canada media liaison

26.1 The Health Products and Food Branch will ask an official from Health Canada's Public Affairs, Consultation and Regions Branch to coordinate media requests for information on the proceedings of a public forum. The official will also coordinate media requests to talk with a spokesperson from the Branch and the advisory body, if applicable, and with presenters who are available.

Posting of public input

27.1 The Health Products and Food Branch requires consent to make third-party information available to the public. It will post the public input it receives through a public forum on its Web site as soon as possible and subject to the consent of third parties. The posted information will include

a. the name of the person or organization that provided information;

b. the expertise, affiliations, and interests of the person or organization, if provided on the Voluntary Statement of Information for Public Involvement;

c. the type of information provided, such as scientific research, published report, or personal information;

d. a one-line summary of the information; and

e. the actual information the presenter provided, if available in writing.

Summary of a public forum

28.1 The Health Products and Food Branch will prepare, or have a third party prepare, a summary of a public forum. In addition to the requirements of paragraph 7.1 of the Policy, the summary will include an overview of stakeholder participation in the public forum.

Availability of the public forum report

29.1 The Health Products and Food Branch will post the public forum report on the Health Canada Web site. It will also provide a copy to presenters and any advisory body with a related mandate.

Advance copy for sponsor or manufacturer

30.1 For information-sharing purposes only, the Health Products and Food Branch will provide a final public forum report to the sponsor or manufacturer 48 hours before its public release.

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.

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.