



Health  
Canada

Santé  
Canada

*Your health and  
safety... our priority.*

*Votre santé et votre  
sécurité... notre priorité.*

**2007**

Health Products and Food Branch

# **Guidance on Advisory Bodies**

**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.

This Guidance document 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](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](http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/public-rev-exam/index_f.html)

For further information please contact:  
Office of Consumer and Public Involvement (OCAPI)  
Health Products and Food Branch  
Health Canada  
Ottawa, Ontario K1A 0K9  
Tel: 613-941-4366  
E-Mail: [ocapi-bpcp@hc-sc.gc.ca](mailto:ocapi-bpcp@hc-sc.gc.ca)



© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2007  
This publication may be reproduced without permission, provided the source is fully acknowledged.

## Table of Contents

Background .....	iii
About this Guidance .....	iv
Note to Contributors .....	vi
<b>What’s “New and Transparent” about the Guidance on Advisory Bodies?</b> .....	<b>vii</b>
<b>Section 1: Use of Advisory Bodies</b> .....	<b>1</b>
Application of the Guidance on Advisory Bodies .....	1
Role of an advisory body .....	1
Terms of reference .....	1
Questions for an advisory body .....	1
<b>Section 2: Members</b> .....	<b>2</b>
Number of members .....	2
Appointment of members .....	2
Appointment of the chair .....	2
Membership considerations .....	2
Variety of perspectives .....	2
Demographic representation .....	3
Input into appointments .....	3
Security clearance .....	3
Types of members .....	3
<b>Section 3: Non-Members</b> .....	<b>4</b>
Invited guests .....	4
Contracted experts for specific purposes .....	4
Federal employee participation on an advisory body .....	4
Privacy of advisory body meetings .....	4
Observers .....	4
Request to observe advisory body meetings .....	5
Federal employee observing an advisory body meeting .....	5
<b>Section 4: Affiliations and Interests</b> .....	<b>6</b>
Compulsory disclosure of affiliations and interests .....	6
Direct financial interest .....	6
Direct financial interest: exclusion from membership .....	6
Direct financial interest: limited participation .....	6
Advisory bodies: affiliations and interests .....	6
Range of affiliations and interests .....	7
Disclosure of affiliations and interests at meetings .....	7
Limited participation of advisory body member .....	8
Confidentiality of information .....	8
Transparency of membership .....	8
Timing of membership information disclosure .....	8
<b>Section 5: Roles and Responsibilities</b> .....	<b>10</b>
Responsibilities of members .....	10
Responsibilities of the chair .....	10
Commitment to confidentiality .....	11
Executive Secretary .....	12

---

Secretariat .....	12
Responsibilities of the advisory body secretariat .....	12
Considering all input .....	12
Role of an advisory body with a public input process .....	13
Media .....	13
<b>Section 6: Reporting to the Public.....</b>	<b>14</b>
Reporting to the public.....	14
Confidential business information .....	14
Advisory body report: policy, management, and program development .....	14
Advisory body report: pre-market without a public input process.....	15
Advisory body report: pre-market with a public input process.....	15
Advisory body report: post-market.....	15
Report timing and standards .....	16
<b>Section 7: Administration.....</b>	<b>17</b>
Official languages .....	17
Indemnification of members: when serving as volunteers .....	17
Indemnification of members: when receiving payment for time .....	17
Travel and expenses .....	17
Process for resignation .....	17
Reasons for termination .....	17
<b>Glossary.....</b>	<b>18</b>
<b>Additional Resources .....</b>	<b>21</b>

## Background

Health Canada's commitment to openness and transparency is articulated in the Department's Report on Plans and Priorities (RPP) and in the Health Products and Food Branch's Strategic Plan for 2007–12. It is also rooted in a variety of existing policies, including the Government of Canada Communications Policy, Health Canada's Policy Toolkit for Public Involvement, and the Health Products and Food Branch's Public Involvement Framework. As such, the Branch is committed to a decision-making process that involves patients, consumers, health professionals, industry, and researchers.

Under the Blueprint for Renewal initiative, the Health Products and Food Branch is undertaking a comprehensive review of its approach to regulating health products and food. The Branch's *Review of Regulated Products: Policy on Public Input* and this *Guidance on Advisory Bodies* have been drafted in parallel and represent deliverables under this initiative.

## About this Guidance

The Health Product and Food Branch's *Review of Regulated Products: Policy on Public Input* and this guidance document replace Health Canada's *Policy Guide on the Management of Advisory Committees*. The Branch has adopted this *Guidance on Advisory Bodies* to more accurately reflect its regulatory responsibilities and commitment to a more open and transparent advisory body process.

This guidance sets out best practices and standards for establishing and managing advisory bodies. It is based on independent evaluations of the Health Products and Food Branch's advisory body processes, international best practices, a literature review, and the Branch's experience with public involvement activities. It also draws on, and is consistent with, existing federal policies and frameworks, including those governing science and risk-based decision making, public engagement, communications, and access to information.

This *Guidance on Advisory Bodies* is applicable to all advisory bodies in the Branch, including advisory bodies established to provide advice on matters of policy, management, and program development, and bodies providing advice on specific matters relating to the review of a regulated product. Although the standards and best practices within this guidance apply to all types of advisory bodies, there are slight, yet important differences in approach for an advisory body providing advice on a regulated product. For instance, information management practices for these types of bodies must also take into account the management of confidential business information.

Recognizing the complex and diverse nature of the Branch's work, this guidance allows for flexibility in addressing circumstances when different arrangements for advisory bodies may have to be made. The Branch may decide to work outside these practices and standards under exceptional circumstances, which should be documented.

This guidance is intended to provide direction to Health Products and Food Branch staff on the management of advisory bodies, while also providing stakeholders with accessible information on what to expect when the Branch seeks advice from an external advisory body.

The *Guidance on Advisory Bodies*, the Branch's *Policy on Public Input*, and related guidance documents continue to be "living" documents. Should you have feedback you would like to share, based on your experience in using these tools, please contact:

Manager, Policy, Planning and Analysis  
Office of Consumer and Public Involvement  
Tel: 613-941-4366  
E-mail: [ocapi-bpcp@hc-sc.gc.ca](mailto:ocapi-bpcp@hc-sc.gc.ca)

**Susan Gardner-Barclay**  
Director General  
Office of Consumer and Public Involvement

## Note to Contributors

Many people contributed their knowledge and experience to this guidance and we are deeply grateful for their contribution. Thank you to everyone who had a part in the process, and especially to the following Health Canada staff who worked diligently over the last months to get us here.

Alana Andrews  
Barbara Benning  
Carol Toone  
Dorothy Corbett  
Eric Ormsby  
Erin Lepine  
Glenn E Rivard  
Irene Abou Hamad  
Jane Kolbe  
Jason King  
Julie Desrosiers  
Linda Barber  
Lindsay Blaney  
Marilyn Davis  
Mary Ormerod  
Rebecca Marland  
Stephanie Mehta  
Tilak Gunawardhane  
Victoria Anderson-Selst

## What's "New and Transparent" about the Guidance on Advisory Bodies?

The *Guidance on Advisory Bodies* reflects the Health Products and Food Branch's continued commitment to transparency as an operating principle. Through HPFB's *Review of Regulated Products: Policy on Public Input* and this guidance, the Branch has adopted new and transparent processes in the management of advisory bodies.

- ✓ The Branch will seek a variety of perspectives to sit as advisory body members, including consumers and patients, and will publish the membership list.
- ✓ The Branch will publish a summary of affiliations and interests of all members.
- ✓ Members will give a verbal statement of their affiliations and interests at the beginning of an advisory body meeting.
- ✓ The Branch will provide more opportunities for public input to be considered by advisory bodies.
- ✓ The Branch will publish information about advisory body meetings in the form of minutes, records of proceedings, or formal reports.

## Section 1: Use of Advisory Bodies

- |   |     |  |
|---|-----|--|
| <b>Application of the Guidance on Advisory Bodies</b> | 1.1 | For the purposes of the guidance, the term “advisory body” is used to refer to any external group that is being asked for advice, for example, a board, committee, panel, reference group, or task team.   |
| <b>Role of an advisory body</b>                       | 1.2 | The role of an advisory body is to advise the Health Products and Food Branch on matters of policy, management, program development, or on specific matters relating to the review of a regulated product. The Branch always retains decision-making authority and responsibilities. |
| <b>Terms of reference</b>                             | 1.3 | The Health Products and Food Branch sets out the terms of reference and mandate for an advisory body. The terms of reference must explicitly recognize that the Branch retains decision-making authority.  |
| <b>Questions for an advisory body</b>                 | 1.4 | The Branch will provide the advisory body with questions to address gaps or issues for which the Branch requires additional information. This may include asking for advice on questions related to a regulated product.   |
|   | 1.5 | The advisory body may provide advice in the form of minutes, records of proceedings, or a formal report.   |

---

## Section 2: Members

- Number of members** 2.1 An advisory body must have at least 3 core members, and it should have no more than 25.
- Appointment of members** 2.2 The Health Products and Food Branch appoints members of an advisory body. In considering whom to appoint, the Branch will follow the appointment considerations listed in paragraphs 2.4–2.9.
- Appointment of the chair** 2.3 The Health Products and Food Branch appoints the chair of an advisory body.
- Membership considerations** 2.4 The mandate of an advisory body determines its membership. The Health Products and Food Branch will seek members with the required expertise or experience related to the advisory body’s mandate.
- 2.5 In addition to the required expertise or experience of members, the Branch will also consider
- a. professional standing,
  - b. affiliations and interests,
  - c. demonstrated ability to work in a committee environment,
  - d. demonstrated ability to keep an open mind, and
  - e. demonstrated ability to exercise independent judgment.
- Variety of perspectives** 2.6 The Health Products and Food Branch will seek a variety of perspectives within an advisory body to ensure that advice it receives is comprehensive. Members of an advisory body may include
- a. scientists;
  - b. researchers, academics, and individuals with specialized expertise, such as ethicists;
  - c. leading experts, professionally recognized as such in their fields;

- d. health professionals, including those who have practical or clinical experience with a regulated product;
- e. consumers, patients, caregivers, and those with practical experience or expertise on relevant consumer or patient issues; and
- f. industry stakeholders, except where the advisory body’s mandate is to provide advice on specific matters relating to the review of a regulated product.

**Demographic representation** 2.7 In appointing advisory body members, the Health Products and Food Branch is committed to diversity and inclusiveness. For example, it may select members from specific population groups or geographic locations, when appropriate.

**Input into appointments** 2.8 In considering whom to recruit to an advisory body, the Health Products and Food Branch may

- a. consult with Health Canada staff;
- b. consult with other government organizations;
- c. consult with external organizations, associations, or experts;
- d. consult with the chair and members already on the advisory body; and/or
- e. ask the public for suggestions.

**Security clearance** 2.9 As a condition of appointment to an advisory body, all members must undergo a security clearance to the “reliability status” level.

**Types of members** 2.10 A core member is a permanent member of the advisory body for a specific term outlined in the terms of reference.

2.11 An *ad hoc* member is invited by the advisory body chair or the secretariat to attend meetings or to join the advisory body for a defined period to provide input on a topic or agenda item. An *ad hoc* member must follow the same rules and procedures as a core member.

## Section 3: Non-Members

- Invited guests** 3.1 The Health Products and Food Branch, or the chair in consultation with the Branch, may invite individuals with particular expertise or experience to provide input on a specific topic or agenda item. However, an invited guest may not participate in the formulation of advice or recommendations to the Branch.
- Contracted experts for specific purposes** 3.2 To fulfill an advisory body's mandate or to address a specific question from the Health Products and Food Branch, the chair may ask the secretariat to contract with an expert in a given field to provide additional information to the advisory body. This information may be in the form of a report or presentation. A contracted expert may not participate in the formulation of advice or recommendations to the Branch.
- 3.3 For contracted experts, the secretariat will develop a clear statement of work, with measurable deliverables, and adhere to the Treasury Board Secretariat's *Contracting Policy* (see [www.tbs-sct.gc.ca/Pubs\\_pol/dcgpubs/Contracting/contractingpol\\_e.asp](http://www.tbs-sct.gc.ca/Pubs_pol/dcgpubs/Contracting/contractingpol_e.asp)).
- Federal employee participation on an advisory body** 3.4 To preserve the independence of the federal government as regulatory decision maker, a federal employee may not be a member of an advisory body that is providing advice on specific matters relating to the review of a regulated product. However, a non-Health Canada federal employee may be a member of an advisory body that has a policy, management, or program mandate, as long as the employee is acting in an independent capacity and is not representing the government.
- Privacy of advisory body meetings** 3.5 Generally, advisory body meetings are held in private to provide the greatest opportunity for a full and frank discussion among members, and to protect confidential business information.
- Observers** 3.6 The Health Products and Food Branch, or the chair in consultation with the Branch, may allow individuals, organizations, or

members of the general public to observe an advisory body meeting, or parts of a meeting.

**Request to observe advisory body meetings**

3.7 The Health Products and Food Branch will assess and forward to the chair for consideration any requests from the public to observe an advisory body meeting, or parts of a meeting, that it receives. A response will be provided to the requestor by phone or in writing as soon as a decision has been made, and will include the reasons for the decision.

**Federal employee observing an advisory body meeting**

3.8 A limited number of federal employees may be permitted to observe an advisory body meeting. Priority consideration will be given to those officials whose duties are of relevance to the mandate of the advisory body.

## Section 4: Affiliations and Interests

- |   |     |   |
|---|-----|---|
| <b>Compulsory disclosure of affiliations and interests</b>  | 4.1 | To be considered for appointment, potential members of an advisory body must complete and return the <i>Affiliations and Interests Declaration Form for Advisory Body Members</i> by a deadline determined by the Health Products and Food Branch. A potential member must disclose on the form all affiliations and interests, including any direct financial interest of relevance to the mandate of the advisory body. |
| <b>Direct financial interest</b>                            | 4.2 | A direct financial interest refers to when a person, a person's spouse/partner, or a person's dependent minor child has a direct financial interest in the outcome of the review, through current employment, investments in companies, partnerships, equity, royalties, joint ventures, trusts, real property, stocks, shares, or bonds.   |
| <b>Direct financial interest: exclusion from membership</b> | 4.3 | A person with a direct financial interest in the outcome of a review of a regulated product 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 Health Products and Food Branch considers direct financial interest in a product review to be a conflict of interest.  |
| <b>Direct financial interest: limited participation</b>     | 4.4 | 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.                               |
| <b>Advisory bodies: affiliations and interests</b>          | 4.5 | 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 paragraph 4.2, has 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.

**Range of affiliations and interests**

- 4.6 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 need to ensure that the advice the advisory body gives the Branch is credible.
- 4.7 In addition to direct financial interests, potential advisory body members must also disclose the following affiliations and interests if they are relevant to the mandate of the advisory body:
- a. any payment received from the regulated industry in relation to work done or being done, including past employment, contracts, and consulting;
  - b. any financial support received from the regulated industry, including research support, personal education grants, contributions, fellowships, sponsorships, and honoraria;
  - c. participation in an activity sponsored by the regulated industry, such as a clinical trial, conference, meeting, speaking engagement, or other event;
  - d. any materials, discounted products, or other benefits, such as travel and accommodation, and gifts received from the regulated industry;
  - e. any published or publicly stated point of view on a regulated product or on issues related to an advisory body's mandate; and
  - f. any formal advice or opinion previously given to industry, a government organization, or a non-governmental organization on a matter of relevance to the advisory body's mandate.

**Disclosure of affiliations and interests at meetings**

- 4.8 In addition to requiring advisory body members to disclose affiliations and interests in the *Affiliations and Interests Declaration Form for Advisory Body Members*, the Health

Products and Food Branch or the chair of an advisory body may also ask members to make a verbal statement of their relevant affiliations and interests at the beginning of a meeting.

- |  |      |  |
|--|------|--|
| <b>Limited participation of advisory body member</b> | 4.9  | The Health Products and Food Branch, or the chair of an advisory body in consultation with the Branch, may limit the participation of an advisory body member in a meeting, depending on the nature of the member's affiliations or interests.   |
| <b>Confidentiality of information</b>                | 4.10 | In keeping with the <i>Privacy Act</i> , a completed <i>Affiliations and Interests Declaration Form for Advisory Body Members</i> is confidential. The Health Products and Food Branch will not make public any information in the form without the member's permission.   |
| <b>Transparency of membership</b>                    | 4.11 | The Health Products and Food Branch will be transparent about the membership of its advisory bodies. As a condition of appointment, advisory body members will allow the Branch to publish on its Web site a <i>Summary of Expertise, Experience, and Affiliations and Interests</i> . The Branch prepares the <i>Summary</i> , based in part on the <i>Affiliations and Interests Declaration Form for Advisory Body Members</i> completed by each member. Advisory body members will be asked to review the content of the <i>Summary</i> for accuracy before its release.                           |
|  | 4.12 | For advisory bodies formed before May 11, 2007, the date this <i>Guidance on Advisory Bodies</i> came into effect, the Health Products and Food Branch will publish on its Web site a short biography of members, including expertise or experience relevant to the advisory body's mandate. However, if an advisory body formed before this date is required to consider information from the public through a public input process, advisory body members will be expected to allow the Branch to publish their name and a <i>Summary of Expertise, Experience, and Affiliations and Interests</i> . |
| <b>Timing of membership information disclosure</b>   | 4.13 | The membership and expertise on an advisory body could signal to competitors that a product has been submitted by a sponsor for  |

regulatory review. The Branch will not publish advisory body information if the advisory body is providing advice on issues related to the review of a regulated product for which the Branch has not yet provided market authorization, unless the advisory body will be involved in a broad public input process.

---

## Section 5: Roles and Responsibilities

### Responsibilities of members

- 5.1 Members of an advisory body have a responsibility to Canadians to offer their independent and objective advice to the Health Products and Food Branch. Other responsibilities include the following:
- a. being available and prepared to participate in advisory body meetings;
  - b. being available and prepared to attend a public input activity related to the advisory body's mandate, if necessary;
  - c. participating in discussions before the advisory body prepares its report to the Health Products and Food Branch;
  - d. notifying a Branch official and the chair of any changes in the status of their affiliations and interests relevant to the advisory body mandate, during the advisory body process; and
  - e. making a verbal statement of affiliations and interests at the beginning of a meeting, if asked by the Branch or the chair of the advisory body.

### Responsibilities of the chair

- 5.2 In addition to all the responsibilities of an advisory body member, the chair is responsible for the following:
- a. overseeing and chairing advisory body meetings;
  - b. consulting with the Branch to determine when public input is needed and how it will be sought;
  - c. deciding if all, or part of, an advisory body meeting should be held in private, in consultation with and subject to particular requests from the Branch;
  - d. providing input to the Branch on the selection of advisory body members;
  - e. consulting with the Branch to end the appointment of an advisory body member;

- f. consulting with the Branch to determine whether to limit the participation of an advisory body member in a meeting, depending on the nature of the person’s affiliations or interests (see Limited participation of an advisory body member, paragraph 4.9).
- g. coordinating the work of the advisory body;
- h. facilitating discussion among advisory body members in answering the Branch’s questions before preparing advice or recommendations for the Branch;
- i. ensuring that all advisory body members agree with, or note their disagreement with, the advice in the advisory body report to the Branch;
- j. preparing and delivering the advisory body report to the Branch; and
- k. supporting, in any other way, the advisory body’s mandate.

**Commitment to confidentiality**

- 5.3 Every person must sign a confidentiality agreement before participating in an advisory body, as a member, invited guest, observer, or resource person. The agreement prohibits the disclosure of any protected information received through participation in an advisory body, including information received orally or in writing.
- 5.4 The Health Products and Food Branch will mark information according to the level to which it is protected under the *Government Security Policy*.
- 5.5 The chair of the advisory body will ensure that everyone participating in an advisory body meeting, telephone discussion, e-mail exchange, or in another form of communication has received clear instructions on the confidentiality of the proceedings.

- 
- Executive Secretary** 5.6 The Executive Secretary is the Assistant Deputy Minister, Director General, or authorized delegate who makes decisions about the advisory body and its advice.
- Secretariat** 5.7 A secretariat will be provided to support the advisory body.
- Responsibilities of the advisory body secretariat** 5.8 The advisory body secretariat liaises between members and the Branch and acts as a resource for advisory body members. The secretariat provides leadership and strategic advice in the management of the advisory body and works closely with the chair. In addition, the secretariat
- a. coordinates preparation of the meeting agendas and minutes, records of proceedings and reports, and maintains any information about the advisory body, its mandate, or work that may be posted on the Health Canada Web site;
  - b. coordinates the processes for the *Affiliations and Interests Declaration Form for Advisory Body Members* and security clearance;
  - c. coordinates preparation of information for the advisory body and marks it according to the level to which it is protected under the *Government Security Policy*;
  - d. maintains a list of forward agenda items and nominees;
  - e. coordinates requests for travel reimbursement;
  - f. helps to prepare the advisory body member designated as media spokesperson, if appropriate (see Media, paragraph 5.13);
  - g. monitors and evaluates the efficiency and effectiveness of the advisory body; and
  - h. carries out additional duties as appropriate in support of the advisory body.
- Considering all input** 5.9 The Branch will require an advisory body to consider information that is relevant to its mandate. This may include information that

the Branch has received from the public during a public input process, for instance, through meetings, interviews, public forums, or in writing.

5.10 When an advisory body is required to consider public input received through a broad public input process as part of a product review, the Branch will follow its *Review of Regulated Products: Policy on Public Input* and related guidance documents, which provide direction on notifying the public of the opportunities, type, and timing of a public input process; releasing information about a regulated product; and reporting on public input.

**Role of an advisory body with a public input process**

5.11 When the Health Products and Food Branch decides to seek broad public input on a topic related to the mandate of an advisory body, it will consult with the chair of the advisory body on the process to be used and the organization of the public input activity. Members of the advisory body will attend the public input activity.

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

**Media** 5.13 When appropriate, the Health Products and Food Branch and the chair will, by mutual agreement, appoint a member of the advisory body to be the media spokesperson for the advisory body.

## Section 6: Reporting to the Public

- |  |  |
|--|--|
| <b>Reporting to the public</b>   | <p>6.1 Advisory bodies may be involved in pre-market reviews, which are confidential, or be required to review and discuss confidential business information as part of their work, whether pre- or post-market. This affects how advisory body information is reported to the public. As a result, both the contents and approach to reporting will vary, depending on whether the role of the advisory body is to advise the Health Products and Food Branch on matters</p> <ul style="list-style-type: none"> <li>a. of policy, management, or program development;</li> <li>b. relating to the review of a regulated product for which market authorization has not yet been granted (pre-market); or</li> <li>c. relating to the review of a regulated product for which market authorization has previously been granted (post-market).</li> </ul> |
| <b>Confidential business information</b>                                 | <p>6.2 Confidential business information is protected by Canadian laws and policies, and international treaties. For both 6.1 b. and c., the Health Products and Food Branch will follow Section 4 of its <i>Review of Regulated Products: Policy on Public Input</i> and related <i>Guidance on Information Supporting the Public Input Process</i>, which provide direction on the release of information about a regulated product, including confidential business information.</p>  |
| <b>Advisory body report: policy, management, and program development</b> | <p>6.3 Confidential business information is not normally disclosed to advisory bodies involved in policy, management, and program development. As a result, the Health Products and Food Branch will publish on its Web site the minutes,</p>  |

record of proceedings, or formal report of the advisory body as soon as possible.

**Advisory body report: pre-market without a public input process**

6.4 The existence of an advisory body involved in the review of a pre-market product submission and significant portions of the information it reviews are considered confidential business information. As a result, the Health Products and Food Branch will not publish information about the advisory body meeting until the Branch grants the product a market authorization. Published information on the authorization decision will include the fact that an advisory body was convened and its purpose.

**Advisory body report: pre-market with a public input process**

6.5 When public input has been sought on a pre-market product submission, industry has consented to disclose the existence of the submission and certain information that might otherwise be protected. When an advisory body has considered information received from the public through a pre-market public input process, the Branch will publish on its Web site the minutes, or record of proceedings, or formal report of the advisory body as soon as possible and according to Section 4 of its *Review of Regulated Products: Policy on Public Input*.

**Advisory body report: post-market**

6.6 Some confidential business information must continue to be protected following market authorization. When an advisory body has been involved in the post-market review of a product, the Health Products and Food Branch will publish on its Web site the minutes, record of proceedings, or formal report of the advisory body as soon as possible and according to Section 4 of the *Review of Regulated Products: Policy on Public Input*.

- Report timing and standards**
- 6.7 Reports will be published after the advisory body has approved the content. Reports posted online will be available in both official languages and will comply with Treasury Board's *Common Look and Feel Standards for the Internet*, (see [www.tbs-sct.gc.ca/clf-nsi/index\\_e.asp](http://www.tbs-sct.gc.ca/clf-nsi/index_e.asp)), Health Canada's *Guidelines for Presentation of Reports and Publications*, and Health Canada's *Guidelines for Presentation of Public Involvement Activities and Consultations*.

## Section 7: Administration

- Official languages** 7.1 The provisions of the *Official Languages Act* are relevant to this guidance.
- Indemnification of members: when serving as volunteers** 7.2 In keeping with the Treasury Board’s *Policy on the Indemnification of and Legal Assistance for Crown Servants* (see [www.tbs-sct.gc.ca/pubs\\_pol/hrpubs/TB\\_851/pila\\_e.asp](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/TB_851/pila_e.asp)) and the *Volunteers Policy* (see [www.tbs-sct.gc.ca/Pubs\\_pol/hrpubs/vp-pb/vp-pb\\_e.asp](http://www.tbs-sct.gc.ca/Pubs_pol/hrpubs/vp-pb/vp-pb_e.asp)), advisory body members are eligible for the same protection against personal civil liability as federal employees when faced with comparable risks while acting within the mandate of the advisory body and serving as volunteers.
- Indemnification of members: when receiving payment for time** 7.3 Members of an advisory body receiving honoraria, or other forms of payment, to compensate their time on an advisory body are not serving as volunteers and are not eligible for protection under the Treasury Board’s *Policy on the Indemnification of and Legal Assistance for Crown Servants*. Obtaining legal coverage under these circumstances is the responsibility of individual members.
- Travel and expenses** 7.4 Members will be reimbursed for expenses incurred during their work on an advisory body, such as travel and accommodation, according to Treasury Board’s *Travel Directive* (see [www.tbs-sct.gc.ca/pubs\\_pol/hrpubs/TBM\\_113/td-dv-1\\_e.asp](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/TBM_113/td-dv-1_e.asp)) and *Hospitality Policy* (see [www.tbs-sct.gc.ca/pubs\\_pol/hrpubs/TBM\\_113/HOSP\\_e.asp](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/TBM_113/HOSP_e.asp))
- Process for resignation** 7.5 Advisory body members will provide the Branch with 14 days’ notice of their intent to resign. The resignation notice must be in writing and be addressed to the advisory body secretariat and to the chair. The letter should state the effective date of resignation.
- Reasons for termination** 7.6 A member’s failure to act according to the advisory body’s terms of reference may give cause for termination. If this is the case, the Branch will advise the member in writing, stating the reason for the termination and the effective date.

## 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.
Chair	An appointed advisory body participant who chairs the meetings and is the leader, facilitator, team builder, and principal architect and integrator of the advisory body advice. The chair works closely with the secretariat.
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.
Confidentiality	The attribute that information must not be disclosed to unauthorized individuals, whether deliberately or accidentally, because of the resulting injury to national or other interests with reference to specific provisions of the <i>Access to Information Act</i> and the <i>Privacy Act</i> .
Consumer groups	Consumer groups represent users or purchasers of the products or services that the Branch and/or Health Canada regulates. They are a segment of the public.
Health professional associations	Health professional associations include, but are not restricted to, physicians, nurses, pharmacists, dentists, hospital administrators, natural health practitioners, and alternative medicine practitioners. They are a segment of the public.
Manufacturer	A person, association, or partnership that sells food or a drug under its own name, design, word mark, trade name, or other name, word, or mark that it controls.
Openness	Openness is inviting, hearing, considering, and sharing information in the conduct of the Health Product and Food Branch's business.

Openness is shaped by principles of equal opportunity for participation, relationship building, timeliness, planning, support, capacity, clarity, shared responsibility, accountability, and innovation.

Patient groups	Patient groups represent individuals who require or who are under medical care. A patient may also be a consumer. However, not all consumers are patients. Patients are a segment of the public.
Protected information	Information in the national interest that may qualify for an exemption or exclusion under the <i>Access to Information Act</i> or the <i>Privacy Act</i> , and the compromise of which would reasonably be expected to cause injury to a non-national interest.
Public	In this guidance, 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.
Public involvement	Public involvement refers to interactions between the public and the decision-making body (for example, Health Canada) and includes surveys, focus groups, feedback on discussion documents, public consultation, dialogue, workshops, advisory boards, and partnerships.
Regulated product	Pharmaceuticals, medical devices, biologics and genetic therapies, natural health products, veterinary drugs, food products, and classes of products.
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.

**Transparency** Transparency is facilitating access to and understanding of the decisions made by the Health Products and Food Branch and the information and processes the Branch uses to conduct its business. Transparency is shaped by principles of relevance, clarity, accountability, timeliness, and equal opportunity to access information.

## Additional Resources

Health Products and Food Branch Review of Regulated Products:  
Policy on Public Input

[www.hc-sc.gc.ca/ahc-asc/branch-dirigen/hpfb-dgpsa/public-rev-exam/rev\\_reg\\_prod-exa\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/branch-dirigen/hpfb-dgpsa/public-rev-exam/rev_reg_prod-exa_e.html)

Guidance on Notice of the Public Input Process

Guidance on Information Supporting the Public Input Process

Guidance on Reporting on Public Input

Guidance on Public Forums

[www.hc-sc.gc.ca/ahc-asc/branch-dirigen/hpfb-dgpsa/public-rev-exam/rev\\_reg\\_guide\\_e.html](http://www.hc-sc.gc.ca/ahc-asc/branch-dirigen/hpfb-dgpsa/public-rev-exam/rev_reg_guide_e.html)

Government of Canada Communications Policy

[www.tbs-sct.gc.ca/pubs\\_pol/sipubs/comm/comm\\_e.asp](http://www.tbs-sct.gc.ca/pubs_pol/sipubs/comm/comm_e.asp)

Government of Canada Security Policy

[www.tbs-sct.gc.ca/pubs\\_pol/gospubs/TBM\\_12A/gsp-psg\\_e.asp](http://www.tbs-sct.gc.ca/pubs_pol/gospubs/TBM_12A/gsp-psg_e.asp)

Treasury Board Common Look and Feel Standards for the Internet

[www.tbs-sct.gc.ca/clf-nsi/index\\_e.asp](http://www.tbs-sct.gc.ca/clf-nsi/index_e.asp)

Treasury Board Volunteers Policy

[www.tbs-sct.gc.ca/Pubs\\_pol/hrpubs/vp-pb/vp-pb\\_e.asp](http://www.tbs-sct.gc.ca/Pubs_pol/hrpubs/vp-pb/vp-pb_e.asp)

Treasury Board Travel Directive

[www.tbs-sct.gc.ca/pubs\\_pol/hrpubs/TBM\\_113/td-dv-1\\_e.asp](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/TBM_113/td-dv-1_e.asp)

Treasury Board Contracting Policy

[www.tbs-sct.gc.ca/Pubs\\_pol/dcgpubs/Contracting/contractingpol\\_e.asp](http://www.tbs-sct.gc.ca/Pubs_pol/dcgpubs/Contracting/contractingpol_e.asp)

Treasury Board Hospitality Policy

[www.tbs-sct.gc.ca/pubs\\_pol/hrpubs/TBM\\_113/HOSP\\_e.asp](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/TBM_113/HOSP_e.asp)

Treasury Board Policy on the Indemnification of and Legal Assistance for Crown Servants

[www.tbs-sct.gc.ca/pubs\\_pol/hrpubs/TB\\_851/pila\\_e.asp](http://www.tbs-sct.gc.ca/pubs_pol/hrpubs/TB_851/pila_e.asp)