



Santé Canada



Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Également disponible en français sous le titre: Politique de Santé Canada sur les organismes consultatifs externes (2022).

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Publication date: July 2022

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Cat.: H14-392/2022E-PDF ISBN: 978-0-660-42638-9

Pub.: 210729

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## **OVERVIEW**

#### CONTEXT

The use of external advisory bodies is consistent with the Government of Canada's commitment to seek broad input from Canadians and stakeholders to inform its work and decisions.

External advisory bodies provide Health Canada with expert advice from individuals who have relevant knowledge, expertise, or experience. The advice may relate to scientific, technical, policy, or program matters. Health Canada's advisory body activities are carried out in accordance with the principles and requirements set out in applicable federal government policies and legislation, such as those related to Privacy, Official Languages and Risk Management.

This policy reflects and upholds the principles of openness, transparency and accountability.

### **POLICY OBJECTIVE**

To promote Health Canada's effective and consistent management of external advisory bodies.

#### **AUTHORITY**

This policy is issued under the authority of the Deputy Minister of Health.

#### **APPLICATION**

The policy applies to all situations in which Health Canada - through its branches, directorates and agencies - uses an external advisory body on a long-term or temporary (ad hoc) basis. "External advisory bodies" includes, expert/advisory panels, task groups and committees established with members external to the federal government and selected to provide expert advice.

To the extent no conflict exists, committees established under legislation are also covered by this policy with respect to their management and operations.

An external advisory body may operate outside this policy if supported by the Deputy Minister. In these cases, such as in a public health emergency or when necessary to establish an external advisory body in an expedited manner, the reasons must be documented.

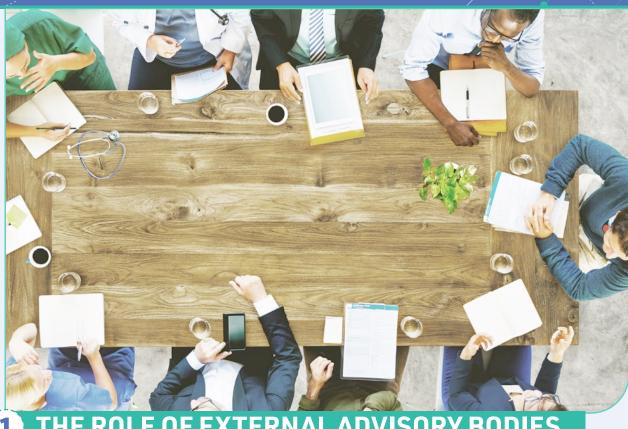
Health Canada will uphold, promote and encourage the use of this policy when co-chairing or jointly managing advisory bodies with other government departments and agencies.

This policy will be reviewed and updated as necessary.

## **DEFINITION OF AN EXTERNAL ADVISORY BODY**

#### THESE ARE THE DEFINING CHARACTERISTICS OF AN EXTERNAL ADVISORY BODY:

- it is established by the Minister(s) or the Department to provide advice on specific medical, scientific, technical, policy, or program matters within the scope of Health Canada's mandate;
- its members are external to the federal government and are selected to provide Health Canada with expert advice; and
- it provides its advice to Health Canada as a group and not as individuals or representatives of organizations.



## THE ROLE OF EXTERNAL ADVISORY BODIES

#### **PURPOSE**

To set out the reasons to establish an external advisory body and to establish its role.

#### **CONTEXT**

Health Canada seeks information and advice in a variety of situations from a variety of individuals, organizations, agencies and governments. Not every group that provides advice to Health Canada is defined as an advisory body. For example, a federal/provincial/territorial committee and an interdepartmental working group are not considered advisory bodies. Advisory bodies are composed of members who are external to the federal government and who are appointed to reflect a wide range of relevant knowledge, expertise and experience. Members act in an advisory capacity to Health Canada specific to the mandate of their advisory body.

#### **PRINCIPLE**

Health Canada decides when to establish an advisory body and defines its mandate, terms of reference, duration and membership. The advisory body provides advice to Health Canada, which Health Canada considers in its work and during its decision-making processes. Health Canada has the ultimate decision-making authority and accountability for all decisions resulting from the advice received from an external advisory body.

#### 1.1 PURPOSE OF AN ADVISORY BODY

Health Canada may establish an advisory body to seek expert advice on medical, scientific, technical, policy, or program matters within Health Canada's mandate.

#### 1.2 AUTHORITY TO ESTABLISH AN ADVISORY BODY

All advisory bodies are to be established with the approval of the Department's Minister(s), Deputy Minister, Assistant Deputy Ministers, or Director Generals.

#### 1.3 REASONS TO ESTABLISH AN ADVISORY BODY

Health Canada may establish an advisory body to receive external advice, including advice on:

- a. policy development and implementation;
- b. program development and implementation;
- c. professional or scientific matters where there is a need to supplement Health Canada's expertise;
- d. a matter for which there is a lack of conclusive data or scientific certainty; and
- e. a matter for which input on a risk and benefit evaluation, including ways to mitigate or minimize risks, would be beneficial.

### 1.4 FACTORS TO CONSIDER

Health Canada considers a variety of factors when deciding whether to establish an advisory body and when determining its mandate. These factors include:

- a. the time and resources available;
- b. the urgency of the matter;
- the availability of people with the required knowledge, expertise, and experience;
- d. the alignment with Health Canada's mandate and to Department and Government priorities; and
- e. the importance of the matter to the health of Canadians.

#### 1.5 MANDATE AND TERMS OF REFERENCE

Every advisory body must have a mandate and terms of reference.

#### 1.6 WRAP-UP OF THE WORK OF AN ADVISORY BODY

Health Canada may end the mandate of an advisory body and disband it at any time for reasons including:

- a. a change in circumstances that causes the advisory body's advice to no longer be required;
- b. a breach of confidentiality or ethics that has undermined the credibility of the advisory body; or
- c. the completion of the advisory body's mandate.

Health Canada will write to advisory body members to notify them of this decision. Refer to chapter 7 for information about the review of a disbanded advisory body.

#### 1.7 HEALTH CANADA RETAINS DECISION-MAKING AUTHORITY

The role of an advisory body is to provide advice and may include recommendations to Health Canada. Health Canada will consider the advice alongside other factors when making decisions. Health Canada has the ultimate responsibility and accountability for all decisions resulting from the advice received from an external advisory body.





To set out the principles respecting the appointment of members to an advisory body.

#### **CONTEXT**

Health Canada invites individuals to be part of an advisory body to share their knowledge, expertise, or experience and to work together to formulate recommendations. In appointing individuals to an advisory body, Health Canada's goal is to have a group with a range of relevant knowledge, expertise and experience to provide the best advice possible.

#### **PRINCIPLE**

Appointments to an advisory body should reflect a broad range of perspectives relevant to its mandate.

#### 2.1 MEMBER SELECTION COMMITTEE

When deciding on appointments to an advisory body, Health Canada may choose to establish a selection committee. A selection committee can provide an effective way to support a fair, equitable, and transparent member recruitment and appointment process.

#### 2.2 APPOINTMENT OF MEMBERS

Health Canada appoints the members of an advisory body and sets a term for the appointment. When deciding on appointments to an advisory body, Health Canada may seek nominees through an open call for nominations of people whose knowledge, expertise, or experience best matches the mandate of the advisory body. Alternatively, Health Canada may contact experts directly based on their expertise, or may seek recommendations for members from previous or current members or associations, organizations, or networks. Health Canada will also consider a person's:

- a. professional standing;
- b. affiliations and interests;
- c. personal suitability;
- d. publicly available information and statements; and
- e. availability.

#### 2.3 NUMBER OF MEMBERS

An advisory body must have at least two members. The optimal number of members will depend on the advisory body's mandate.

## 2.4 KNOWLEDGE, EXPERTISE AND EXPERIENCE OF MEMBERS

When deciding on appointments to an advisory body, Health Canada will seek a range of relevant knowledge, expertise and experience, as appropriate. Depending on its mandate, members of an advisory body may include people who have:

- a. medical, scientific or technical knowledge;
- b. specialized expertise;
- c. recognition as a leader in the field;
- d. practical or clinical experience;
- e. first-hand personal experience as a health professional, patient, people with lived and living experience (PWLLE), consumer, or caregiver;
- f. first-hand business knowledge as, for example, a product developer, manufacturer, or commercial user;
- g. organizational experience representing people who share a point of view or interest; and
- h. any other relevant background that will bring useful input to the advisory body and complement the knowledge, expertise and experience of other members.

#### 2.5 DIVERSITY AND INCLUSION

When deciding on members for a selection committee that will review external advisory body nominations and when appointing members to an external advisory body, Health Canada will consider diverse and inclusive membership and perspectives. For example, members may be sought from different types of stakeholder groups or experts, in addition to specific populations (e.g. racialized communities, LGBTQ2+, persons with disabilities), gender and age groups, official language minority communities, or from a variety of geographic locations. To support the Government of Canada's commitment to reconciliation, selection committees and advisory bodies should carefully consider how to ensure representation of Indigenous Peoples.

#### 2.6 FEDERAL EMPLOYEE PARTICIPATION ON AN ADVISORY BODY

To preserve the independence of the federal government as a decision maker, a federal employee can neither chair nor be a member of an advisory body. In addition, although federal employees may assist in the preparation of reports or other documents that reflect the advice of the members, they cannot participate in the formulation of an advisory body's advice to Health Canada. Refer to chapter 4 for information about the roles and responsibilities of Health Canada employees.

## 2.7 SELECTION OF THE CHAIR(S)

Health Canada appoints the chair(s) of an advisory body for a specific term. The chair(s) may be a member of the advisory body or may be a non-member. A non-member chair does not participate in formulating the advisory body's report and recommendations. A non-member chair's primary role is as a facilitator and coordinator.

Health Canada may also consider the following models for the chair(s) of an advisory body:

- a. vice-chair where a member is appointed, for a specific term, to act on behalf of the chair in the case of the chair's absence or at the request of the chair;
- b. co-chairs, where two members (or non-members) share the responsibilities of the chair;
- rotating chairs where at certain intervals (e.g. every meeting or every year) a new chair is appointed; or
- d. no chair where the responsibilities of the chair are shared across all members of the advisory body.

When appointing chair(s), Health Canada will consider, among other criteria, a person's:

- a. professional standing;
- b. affiliations and interests;
- c. personal suitability; and
- d. availability.

It is recommended that Health Canada document the rationale for the selection of the chair(s).

#### 2.8 SEEKING INPUT ON APPOINTMENTS

When deciding on appointments to an advisory body whose mandate is confidential, Health Canada may consult with:

- a. Health Canada officials;
- b. the Minister(s) and their office(s);
- the advisory body chair(s) and members already appointed to the advisory body; and
- d. other individuals with relevant knowledge, as appropriate.

When deciding on appointments to an advisory body whose mandate is not confidential, Health Canada may go outside the department to other Canadian and international governments or to external organizations and associations to ask for appointment suggestions.

#### 2.9 REQUIREMENT BEFORE APPOINTMENT

Before being appointed as a member of an advisory body, a nominee must:

- a. obtain the security clearance appropriate to the mandate of the advisory body, if required;
- b. sign a Confidentiality Agreement;
- c. complete and sign an Affiliations and Interests Declaration Form and, if participation is permitted despite a direct financial interest, accept limitations on participation as described in chapter 3 of this policy; and
- d. provide a brief autobiography and review and accept a summary of their affiliations and interests (these documents may be made public, including in media releases).

#### 2.10 RESIGNATION

A member may resign from an advisory body by writing to the executive secretary of the advisory body, with a copy to the chair(s), including the effective date of the resignation. It is preferred that the member gives 14 days' notice of their intent to resign.

## 2.11 END OF APPOINTMENT (GENERAL)

An appointment to an advisory body ends when:

- a. the member's term is complete;
- b. the member resigns;
- c. the member becomes a federal government employee;
- d. the mandate of the advisory body has been completed;
- e. the mandate of the advisory body is changed and the member's knowledge, experience, or expertise is no longer relevant to the revised mandate; or
- f. Health Canada and any collaborating government departments, agencies, or organizations decide to rescind the advisory body's mandate and terms of reference.

## 2.12 END OF APPOINTMENT (FOR CAUSE)

Health Canada may end a member's appointment by writing to the member stating the reasons the appointment is being concluded and the effective date when:

- a. the member has failed to act according to the advisory body's terms of reference;
- b. the member has failed to comply with their obligations under the Confidentiality Agreement;
- c. a change in the member's affiliations and interests results in a direct financial interest that prevents participation;
- d. the member has missed three consecutive meetings of the advisory body without informing the secretariat of the reason(s); or
- e. the member has acted in a way that jeopardizes the integrity of the advisory body.



To define affiliations and interests, including a direct financial interest and to clarify when, how and to whom members of an advisory body must disclose these affiliations and interests and in what circumstances they prohibit or limit participation.

#### **CONTEXT**

Health Canada may seek advisory body members with knowledge, expertise and experience that are often gained through research grants, paid work for an interested party, etc. A person's affiliations and interests do not necessarily prevent them from being a member of an advisory body, since their input could nevertheless be valuable to the advisory body's mandate. By asking members to declare their interests and affiliations, the advisory body is operating transparently. However, people with a direct financial interest may not participate in any advisory body discussion or formulation of advice related to that interest.

#### **PRINCIPLE**

Maintaining the credibility of advice provided to Health Canada by an advisory body depends on members of the advisory body disclosing their affiliations and interests. In situations where the mandate and membership of the advisory body is not confidential, a summary of the affiliations and interests of advisory board members will be made public.

#### 3.1 COMPULSORY DISCLOSURE OF AFFILIATIONS AND INTERESTS

Before being appointed to an advisory body, a potential member must complete and submit the Affiliations and Interests Declaration Form within the time frame set out by the advisory body secretariat. A potential member must use the form to disclose all affiliations and interests, including any direct financial interests and other affiliations and interests that relate to the mandate of the advisory body. These might include financial support received from a commercial enterprise, participation in an activity sponsored by a commercial enterprise, or published or publicly stated points of view related to the advisory body's mandate. Members are required to update the secretariat and the chair(s) of any changes to their Affiliations and Interests Declaration Form promptly and on an ongoing basis.

## 3.2 AFFILIATIONS AND INTERESTS MAY NOT NECESSARILY PROHIBIT APPOINTMENT

A person with affiliations and interests related to the mandate of an advisory body may still be appointed as a member of the advisory body. Health Canada strives for a range of relevant knowledge, expertise and experience among advisory body members. Health Canada recognizes that individuals with affiliations and interests related to the mandate of the advisory body have valuable knowledge, expertise, or experience and may have a worthwhile contribution to make to the advisory body's work.

## 3.3 AFFILIATIONS AND INTERESTS: LIMITED PARTICIPATION

Health Canada, after reviewing the Affiliations and Interests Declaration Form and consulting the chair(s), may limit the participation of an advisory body member with respect to an agenda item or meeting topic, depending on the nature of the member's affiliations or interests. Such a member may be asked, for example, to: participate in the discussion but not contribute to or vote on the formulation of recommendation(s); refrain from discussing or voting on a question; or not attend a particular meeting. Members whose participation is restricted in such a way will be provided a rationale by Health Canada and the chair(s).

#### 3.4 DIRECT FINANCIAL INTEREST: DEFINITION

A person has a direct financial interest when the person, the person's spouse or common-law partner, or the person's dependent family member has a direct financial interest in the outcome of the advisory body's work, for example through current employment, investments in companies, partnerships, equity royalties, joint ventures, trusts, real property, stocks, shares, or bonds.

#### 3.5 DIRECT FINANCIAL INTEREST

A person with a direct financial interest in the outcome of the advisory body's work, whether of a program, policy, regulated product, or submission, may not be a member of an advisory body. In this situation, Health Canada considers the direct financial interest to be a conflict that prevents participation in the advisory body.

A person with a direct financial interest in only some aspects of the advisory body's mandate may be a member of the advisory body but may not participate in any discussion or formulation of advice or recommendations with respect to the matters for which the member has a direct financial interest. The member may participate in the advisory body's work with respect to the other aspects of the mandate, such as policy, management, or program development matters.

# 3.6 PROTECTION OF THE COMPLETED AFFILIATIONS AND INTERESTS DECLARATION FORM

In keeping with the *Privacy Act*, the personal information in a completed Affiliations and Interests Declaration Form is protected. A summary of a member's affiliations and interests may be made public with the permission of the member who signed it. The summary must be updated promptly and on an ongoing basis to reflect any changes to the member's Affiliations and Interests Declaration Form.

In preparing the summary to be published, the secretariat must ensure that it includes no information that would allow the identification or re-identification of a member's spouse, common-law partner or dependent family member.

#### 3.7 INFORMATION ABOUT MEMBERS

As a condition of appointment, an advisory body member must give Health Canada permission to publish a brief biography and summary of their affiliations and interests. The potential member will have the opportunity to review and approve the summary for accuracy before publication during the appointment process. The summary will be available by contacting the secretariat or may be published on the Government of Canada website unless the mandate or membership of an advisory body must be kept confidential.

#### 3.8 DISCLOSURE AT MEETING

The chair(s) will ask members to make a verbal statement of their relevant affiliations and interests at the beginning of every meeting.



To clarify the roles and responsibilities of advisory body members and the chair(s), as well as the supporting roles of the secretariat, the executive secretary and other Health Canada branches and officials.

#### CONTEXT

An advisory body is set up to provide advice and recommendations to Health Canada. This complex work requires administrative assistance from departmental officials, but the advisory body itself is responsible for the content of its advice in whatever form it takes.

#### **PRINCIPLE**

The duty of advisory body members is to give their best advice to Health Canada. Through an advisory body secretariat and the executive secretary, Health Canada supports the work of advisory bodies.

#### A. ADVISORY BODY MEMBERS: ROLES AND RESPONSIBILITIES

### 4.1 RESPONSIBILITIES OF MEMBERS

Members of an advisory body have a responsibility to Health Canada and by extension to all Canadians, to give their best advice to Health Canada.

Members of an advisory body also have a responsibility to:

- a. be available and prepared to participate in advisory body meetings, including virtual meetings (e.g. teleconferences, email exchanges, videoconferences);
- be available and prepared to attend a public engagement activity related to the advisory body's mandate and to act as a media spokesperson if requested by the secretariat;
- c. participate in the discussions about the advisory body's recommendations, advice, or report to Health Canada;
- d. consider all the input received that is related to the mandate of the advisory body when preparing their recommendations, advice, or report;
- e. promptly notify the secretariat and the chair(s) of any changes in their affiliations and interests related to the advisory body's mandate during the time they are members of the advisory body; and
- f. direct any media inquiries or public inquires to the secretariat.

## 4.2 COMMITMENT TO CONFIDENTIALITY

Members must commit to confidentiality and ensure they will not disclose any sensitive or confidential information received as part of the member's involvement in the advisory body. Members will be required to sign a Confidentiality Agreement that applies to information received in writing or verbally, including through email correspondence, telephone calls and print materials, as well as during presentations and discussions at advisory body meetings. In some circumstances, the very fact that a given advisory body exists may also be confidential.

## 4.3 RESPONSIBILITIES OF THE CHAIR(S)

Advisory body chair(s) have a responsibility to:

- a. provide input to Health Canada on the selection of advisory body members if required;
- b. chair advisory body meetings;
- c. at the start of each meeting, clarify the purpose and anticipated outcome(s) of the meeting;
- d. invite members to make a presentation at a meeting when relevant and appropriate;
- e. identify when information and discussions should be treated as confidential and clarify expectations of members regarding this information;
- f. ask members to make a verbal statement of their relevant affiliations and interests at the beginning of every meeting;
- g. facilitate a full and open discussion among advisory body members in fulfillment of the advisory body's mandate, including in formulating its recommendations, advice, or report to Health Canada;
- h. seek consensus on the advisory body's advice among all advisory body members and, if there is no agreement, to ensure that the diversity of opinion is noted in meeting records or the report;
- i. deliver the advisory body's advice to Health Canada and ensure the preparation of the meeting records or report;
- j. act as the designated media spokesperson for the advisory body unless another person is designated as the media spokesperson under section 4.5; and
- k. support, in any other way, the fulfillment of the advisory body's mandate.

# 4.4 ROLE OF AN ADVISORY BODY MEMBER IN A PUBLIC ENGAGEMENT PROCESS

When Health Canada decides to seek broad public input on a topic related to the mandate of an advisory body, it will consult with the chair(s) and members of the advisory body on the approach to be used and the organization of the public engagement activity. The views of the EAB will be considered in the planning and implementation of the public engagement activity, as appropriate. The approach will align with the purpose and objective(s) of the activity and best practices as outlined in departmental guidelines on public engagement.

#### 4.5 MEDIA SPOKESPERSON

In accordance with the <u>Policy on Communications and Federal Identity</u>, Health Canada and the chair(s) may designate a spokesperson (e.g. another EAB member, or a designated spokesperson from Health Canada) other than, or in addition to, the chair(s) for media inquiries related to the advisory body.

A member of an advisory body who is not the designated media spokesperson does not have the authority to speak to the media about the work of the advisory body unless the secretariat specifically asks them to do so.

#### 4.6 MEDIA INQUIRIES

Advisory body members are requested to direct all media inquiries about the advisory body's membership, mandate and work to the secretariat, who in turn will contact Health Canada's Media Relations team. The Media Relations Officer will follow up with the designated spokesperson for the EAB.

#### 4.7 SOCIAL MEDIA

Social media content developed by an EAB member, which describes work conducted by the EAB, must be reviewed and approved by the secretariat before being disseminated.

The expectations for members' social media use around the work conducted by the EAB will be outlined in the EAB's terms of reference.

#### **B. HEALTH CANADA: ROLES AND RESPONSIBILITIES**

#### 4.8 EXECUTIVE SECRETARY TO THE ADVISORY BODY

Health Canada will name a senior official to act as the executive secretary to the advisory body. The executive secretary provides guidance to the secretariat. After an advisory body submits advice to Health Canada, the executive secretary will report back to the advisory body on how that advice was used.

#### 4.9 SECRETARIAT

Health Canada will establish a secretariat, made up of Health Canada representatives, to provide organizational and administrative support to each advisory body. The secretariat may also include representatives from other Government of Canada departments and agencies. A working group may be set up to support the secretariat.

#### 4.10 RESPONSIBILITIES OF THE SECRETARIAT

The responsibilities of the secretariat include the following:

- a. coordinate the member appointment process;
- coordinate the preparation and distribution of materials for advisory body members, observers and others, with consideration to sensitive or confidential information;
- c. assist with the work of the advisory body, as required;
- d. provide administrative support to advisory body members;
- e. support public access to information about the advisory body, as appropriate;
- f. act as a liaison between Health Canada and the advisory body, including seeking input from Health Canada's subject-matter experts;
- g. assist the chair(s) in carrying out their responsibilities;
- h. carry out any additional duties as appropriate to support the advisory body, including developing risk assessment and mitigation strategies for the advisory body;
- i. undertake any tasks that the executive secretary delegates to the secretariat;
- j. report to the executive secretary on the advisory body's activities;
- k. assist with a review or audit of the advisory body, as required;
- consult with the chair(s), member or non-member, to consider whom to invite to provide input to the advisory body;
- m. consider whom to invite or accept as an observer to all or part of an advisory body meeting;
- n. discuss whether broader input is needed and how it will be sought;
- determine whether all or part of an advisory body meeting should be held in private;
- p. restrict an advisory body member's participation in a meeting due to the nature of that person's affiliations or interests; and
- q. determine that the mandate of the advisory body has been fulfilled.

## 4.11 ROLE OF HEALTH CANADA'S SUBJECT-MATTER EXPERTS

Health Canada's medical, scientific, technical, program, policy and other subject-matter experts support the work of an advisory body in a variety of ways, including:

- a. preparing background documents such as research summaries and regulatory process overviews;
- b. providing information about government policies and programs;
- c. making a presentation or answering questions at an advisory body meeting; and
- d. reporting to the executive secretary on the actions taken as a result of the advice that the advisory body provided to Health Canada.

#### 4.12 RESPONSIBILITIES OF HEALTH CANADA'S SENIOR MANAGEMENT

Health Canada's senior managers are responsible for implementing this policy through the programs they manage or administer. This responsibility includes:

- a. the governance, management and operations of advisory bodies to support policy development and the regulatory process;
- b. the oversight of resource allocations and expenditures;
- c. the review and audit of advisory bodies; and
- d. collaboration with other governments, agencies and organizations as appropriate to the mandate of the advisory body.

# 4.13 RESPONSIBILITIES OF THE COMMUNICATIONS AND PUBLIC AFFAIRS BRANCH

The Communications and Public Affairs Branch (CPAB) is responsible for providing advice and support on the application of this policy. This includes:

- a. providing advice on the application of this policy to Health Canada programs and initiatives;
- b. monitoring, reviewing and reporting on the implementation of the policy; and
- c. updating the policy with input from Health Canada staff to ensure it remains relevant and reflects departmental priorities and best practices.

Communications advice and support are provided to develop communications materials, respond to media inquiries, publish content on Canada.ca and to coordinate public engagement activities in support of the EAB's mandate.



To clarify the role of individuals who are not advisory body members. This includes, for example, contracted experts, invited guests, government employees and observers.

#### CONTEXT

Health Canada may invite certain individuals who are not advisory body members to provide input on a specific topic or agenda item. As well, individuals may ask to speak to the advisory body on a given topic or agenda item or may ask to observe all or part of a meeting. Their request will be considered by Health Canada, in consultation with the chair(s), and may be granted or refused.

#### **PRINCIPLE**

An advisory body may benefit from input received from others. However, non-members may not participate in formulating advice or recommendations for Health Canada.

#### 5.1 REASONS FOR AN ADVISORY BODY TO HOLD CLOSED MEETINGS

Advisory body meetings may be closed to non-members for a variety of reasons, including to:

- a. provide the greatest opportunity for a full and frank discussion among members;
- b. support the protection of sensitive or confidential information; and
- c. keep deliberations from becoming public before the advisory body decides on its final recommendations.

## 5.2 ATTENDANCE AT MEETINGS

At the discretion of the secretariat and in consultation with the chair(s), meetings of an advisory body may be:

- a. closed to everyone except advisory body members (a non-member chair facilitator is considered an advisory body member for this purpose);
- closed to everyone except advisory body members and Health Canada support staff;
- c. closed to everyone except advisory body members, Health Canada support staff and invited presenters and observers; or
- d. open, when there are no confidential materials or discussions.

## 5.3 REQUEST TO PARTICIPATE IN OR OBSERVE A MEETING

The secretariat, in consultation with the chair(s), will consider all requests (internal and external) to participate in or observe a meeting. The secretariat will respond to the request by telephone or in writing.

### 5.4 INVITATION TO PROVIDE INFORMATION

To fulfill an advisory body's mandate, Health Canada may, after consulting the chair(s), invite an individual with particular expertise or experience to attend a meeting to provide input on a topic or agenda item or to answer a specific question. Invited guests may include:

- a. experts under contract with Health Canada;
- b. federal government employees;
- representatives of corporations and organizations, health professionals and others with information or an interest related to the advisory body's mandate; and
- d. members of the public.

#### 5.5 PRESENTATION OF INFORMATION

The secretariat, in consultation with the executive secretary and chair(s), may invite an individual to provide the advisory body with information through:

- a. a written submission;
- b. an oral presentation at an advisory body meeting; or
- participation in discussions at an advisory body meeting, except for those for formulating advice or recommendations.

#### 5.6 ROLE OF PRESENTERS AND OBSERVERS

Presenters and observers may not participate in discussions at the advisory body meeting unless the chair(s) specifically invites them to do so. Presenters may answer questions related to their presentation, as required. Only advisory body members may participate in the advisory body's formulation of advice or recommendations to Health Canada.

#### 5.7 REQUIREMENTS OF PARTICIPANTS

Before an individual may present information at or observe an advisory body meeting, Health Canada may require the person to complete:

- a. an Affiliations and Interests Declaration Form;
- b. a Confidentiality Agreement; or
- c. a Personnel Screening, Consent and Authorization Form, if required.

#### 5.8 CONTRACT WITH AN EXPERT

When Health Canada engages an expert to provide information to an advisory body, it will:

- a. develop a clear statement of work;
- b. set out the contract deliverables and timelines;
- c. follow the Treasury Board Secretariat's procurement requirements in the <u>Policy on the Planning and Management of Investments</u> and the <u>Directive</u> <u>on the Management of Procurement</u>; and
- d. follow the Government Contracts Regulations.



To clarify how an advisory body provides advice and when information about the advisory body and its work may be made public.

#### CONTEXT

An advisory body's work is often confidential. Health Canada may make public information about the advisory body, its mandate, recommendations, advice, or report, as permitted by law and policy.

#### **PRINCIPLE**

In keeping with Health Canada's openness and transparency policies, EAB members will be informed of how their advice and recommendations are being considered by Health Canada in policy and program decision-making. Advisory body information may be made available to the public. However, in certain circumstances, including the protection of sensitive or confidential information and the possibility of potential or ongoing litigation, it will not always to be possible to make public an advisory body's existence, recommendations, advice, or report.

#### 6.1 INFORMATION TO BE POSTED ONLINE

Unless otherwise determined by Health Canada, information about the EAB and its membership will be made public on Canada.ca as well as, if appropriate, the website of a collaborating department or agency.

Information published online about the advisory body may include:

- a. terms of reference;
- b. membership list;
- c. members' biographies;
- d. summary of affiliations and interests;
- e. secretariat contact information; and
- f. meeting summaries.

If information about the EAB or its membership includes information that is confidential or otherwise sensitive, Health Canada may determine that publication or other disclosure of such information is not appropriate. Such a determination will be reflected in the terms of reference for the advisory body.

## 6.2 INTELLECTUAL PROPERTY

Volunteer members who participate in the preparation of written recommendations or reports must sign an agreement assigning any intellectual property rights in those documents to the Government of Canada.

When external advisory body members are under contract with Health Canada, intellectual property rights in material developed in the course of their participation on the EAB will be specified in the contract.

### 6.3 DOCUMENTATION OF RECOMMENDATIONS AND ADVICE

Advisory bodies are required to capture information about their members, activities, discussions and recommendations or advice. The frequency and format of advisory body reports may vary.

The recommendations and advice from an advisory body may be reported using the following formats, as appropriate:

- a. the minutes of a meeting;
- b. a record of proceedings;
- c. a record of decision; or
- d. a formal report.

The secretariat will prepare a non-attributable document that includes a summary of advisory body discussions or the recommendations and advice resulting from advisory body discussions. This includes in-person meetings, virtual meetings, conference calls and videoconferences. If parts or all of this record are confidential, the document will indicate this.

The draft document will be provided to advisory body chair(s) for review in a timely manner. The chair(s) may consult with the members to confirm the accuracy of the document, as necessary. As soon as is possible, the advisory body will then confirm the draft as an accurate record or will correct it.

A member of an advisory body who did not participate in a portion of a meeting because of affiliations and interests may not receive the section of the document pertaining to those affiliations and interests until that part of the document becomes public.

Members are expected to participate in the advisory body discussions where recommendations and advice are developed in order to contribute to the drafting of the final recommendations.

Recommendations and advice received from an advisory body will be kept in accordance with Treasury Board policies and guidelines.

#### 6.4 DISCUSSION LEADING TO RECOMMENDATIONS OR ADVICE

An advisory body provides its advice to Health Canada as a group and not as individuals or representatives of organizations unless specified to do so in certain circumstances. If members cannot come to a consensus, then the record must note that there is a diversity of opinion with respect to the recommendations or advice.

#### 6.5 ADVICE LINKED TO MANDATE

An advisory body may provide recommendations or advice only in response to questions posed by Health Canada and within the scope of its mandate. Information that Health Canada receives beyond the scope of an advisory body's mandate will be retained and used at the discretion of the Department for future purposes.

#### 6.6 FOLLOW-UP REPORT TO MEMBERS

The executive secretary will provide the chair(s) and advisory body members with information on how their advice and recommendations are considered by Health Canada in policy and program decision-making. This may be communicated in verbal presentations at advisory body meetings, in email updates, or summarized in a final feedback report, as appropriate.



To set out the process for reviewing the purpose and functioning of an advisory body.

#### **CONTEXT**

It is government practice to conduct regular evaluations and audits to verify that government initiatives are cost-effective and achieve expected results. Although advisory bodies are in place to provide advice to Health Canada, their purpose and operation should be periodically reviewed as part of standard accountability procedures.

#### **PRINCIPLE**

The purpose and operation of an advisory body should be periodically reviewed to ensure it is operating effectively and efficiently, to confirm that its work is still required, and to identify opportunities for administrative and management improvements.

#### 7.1 PURPOSE OF THE REVIEW

The purpose of the review is to determine whether administrative, management, or other improvements are required to increase the efficiency and effectiveness of an advisory body. The review may also be carried out to determine the ongoing relevance of the advisory body's mandate, to inform disbanding or renewal decisions or to inform future approaches to the management of EABs within the Department.

#### 7.2 SCOPE OF THE REVIEW

The review may include an examination of the following:

#### A. REVIEW OF CONTENT AND ADMINISTRATIVE FUNCTIONS

- a. the continued relevance of the advisory body's mandate;
- b. the relevance of the membership's knowledge, expertise and experience to the advisory body's mandate;
- c. the extent to which the advisory body is operating in conformity with its terms of reference;
- d. the quality, quantity and relevance of material provided to the advisory body;
- e. the use of input from non-members;
- f. Health Canada's use of the advisory body's advice;
- g. the cost of the advisory body;
- h. the diversity of perspectives reflected in recommendations, advice and reports; and
- i. the secretariat's capacity to provide the necessary administrative support.

#### **B.** REVIEW OF OPERATIONS

- a. the timing, location, frequency and effectiveness of meetings;
- b. the availability of all members to be part of the discussions and the formulation of recommendations and advice;
- c. the timeliness of advice and reporting provided to Health Canada;
- d. the availability of information about the advisory body to the public, if appropriate; and
- e. the timeliness of postings on Canada.ca, if applicable.

#### 7.3 REVIEW APPROACH

The review may be conducted by Health Canada officials or by consultants hired by Health Canada.

A review of an advisory body may include:

- a. an examination of its mandate, terms of reference and work accomplished to date;
- b. an analysis of meeting agendas, minutes and reports;
- c. feedback from advisory body members, secretariat officials, the executive secretary, participants, observers and others through questionnaires, interviews and/or group discussions, etc.;
- d. a financial review of advisory body expenses, including meeting costs, travel expenses and contracts; and
- e. an analysis of Health Canada's processes in response to advice and reports from the advisory body.

## 7.4 TIMING OF THE REVIEW

The timing of a review of an advisory body may be determined by the length of the term of the advisory body.

For advisory bodies with a time-limited mandate (i.e. expected to be disbanded when the mandate has been completed) a review may be initiated when:

- a. the mandate changes;
- b. the membership changes or is renewed;
- c. the mandate is complete; or
- d. there is a request from senior management.

For advisory bodies with an ongoing mandate with no established end date, a review may be initiated:

- a. to validate the continued relevance of the mandate and membership;
- b. if the membership changes or is renewed;
- c. when mandate milestones have been reached; or
- d. once the mandate is complete.

It is at the discretion of the secretariat for an EAB with an ongoing mandate to specify whether reviews are to be conducted according to a set schedule (e.g. bi-annually).

#### 7.5 DISSEMINATION OF THE REVIEW REPORT

The results of the review will be submitted to the executive secretary, who may then authorize its distribution to advisory body members.



To describe the administrative policies that apply to an advisory body.

#### **CONTEXT**

The secretariat handles the administration of the advisory body and must follow the policies, directives, standards and guidelines set out by Treasury Board.

#### **PRINCIPLE**

Although advisory bodies are set up to provide advice to Health Canada, their activities are carried out in accordance with the principles and requirements set out in applicable federal government policies and legislation.

#### 8.1 OFFICIAL LANGUAGES

In keeping with the federal <u>Official Languages Act</u> advisory body members have the right to receive documents and participate in discussions in the official language of their choice.

#### 8.2 TRAVEL AND ACCOMMODATION EXPENSES

Members of an advisory body who travel for authorized advisory body purposes will have their travel and accommodation expenses reimbursed according to the <u>Travel Directive</u> and <u>Directive</u> on <u>Travel</u>, <u>Hospitality</u>, <u>Conference and Event Expenditures</u>.

#### 8.3 RISK ASSESSMENT

The provisions of the Treasury Board <u>Framework for the Management of Risk</u> apply to advisory bodies. As such, Deputy Heads are responsible for managing organizational risks by leading the implementation of effective risk management practices. In the interest of effective management of advisory bodies, branches must evaluate the potential liabilities that their advisory bodies' activities could place upon the Crown. This includes conducting a risk assessment to identify, address and mitigate risks. Advisory body activities must be carried out in accordance with good risk management principles and practices outlined in the Treasury Board Framework and its supporting learning resources.

# 8.4 INDEMNIFICATION OF MEMBERS: WHEN SERVING AS VOLUNTEERS

Health Canada undertakes to provide its volunteer advisory body members with protection against civil liability that arises out of their actions as a member, provided the member acts in good faith, within the scope of their volunteer duties, does not act against the interests of the Crown and does not otherwise have available such protection.

In order for an eligible member to receive protection against civil liability, including for legal costs of defending an action as well as any award of damages against them, volunteer members must give prompt notice to Health Canada of any claim, action, suit or proceeding brought against the member, and must obtain Health Canada's consent, in advance, to the legal counsel selected to represent the volunteer member and any associated costs. Health Canada may, at its own expense and discretion, participate in the conduct of the defence of any such claim, action, suit or proceeding, and any negotiations for the settlement of the same. Health Canada will indemnify the member for payment of any settlement, provided that the member has obtained Health Canada's consent to the settlement.

Members act collectively as an advisor to Health Canada with respect to the mandate of their advisory body but they are not final decision makers. Health Canada has the ultimate responsibility and accountability for any decision resulting from the advice received from an external advisory body.

# 8.5 INDEMNIFICATION OF MEMBERS: WHEN RECEIVING PAYMENT FOR TIME

Members that are paid by way of a service contract for their participation on an advisory body are not eligible for indemnification under this policy. Obtaining appropriate insurance coverage under these circumstances is the responsibility of individual members.

Members appointed to an advisory body and remunerated pursuant to a statutory authority may be eligible for legal assistance and indemnification pursuant to applicable Treasury Board policies.

#### 8.6 REMUNERATION OF MEMBERS: PAYMENT FOR TIME

Health Canada may compensate its advisory body members for their participation on an advisory body. The decision to compensate members must be based on a rationale which may include the requirement for certain expertise, life experience, exceptional scope of work, or other criteria. There is a strong rationale for remunerating members with precarious economic situations, members who are contributing to multiple committees and those who have to give up an hourly wage to participate. Such decisions will be made by the Deputy Minister or a person identified by the Deputy Minister, and in adherence to applicable Treasury Board policies and guidelines for reporting and auditing. The appropriate mechanism to compensate members should be considered in consultation with the Chief Financial Officer Branch.

Statutes may provide that advisory bodies are or may be established by the Minister(s) and that members may be remunerated. Such remuneration may be fixed by the Governor in Council but the relevant provisions may differ from one statute to the other.

#### 8.7 HONORARIA

Health Canada has the discretion to offer an honorarium as a token of appreciation for services that have been provided free of charge. An honorarium should not be used as a replacement for salary and wages, and should be the exception rather than the rule. Each decision to offer an honorarium should be made in consultation with the Chief Financial Officer Branch and should be well documented.

Honoraria are not to be paid to public servants or other public officials already receiving salary for the conduct of public business.

## **APPENDIX A: GLOSSARY**

For the purposes of the Health Canada Policy on External Advisory Bodies, the following words are given the meanings shown in this table.

Word	Meaning
Chair	The person appointed by Health Canada to facilitate the work of the advisory body. The chair may be a member of the advisory body and participate fully in all of the advisory body's work, or may be a non-member whose role is primarily as a facilitator and coordinator.
Commercial enterprise	A corporation, partnership, or other organized business that operates in the marketplace, including buying or selling goods, services, research, or ideas.
Direct financial interest	A person has a direct financial interest when the person, the person's spouse or common-law partner, or the person's dependent family members has a direct financial interest in the outcome of the advisory body's work, through current employment, investments in companies, partnerships, equity royalties, joint ventures, trusts, real property, stocks, shares, or bonds.
Executive secretary	The Health Canada official with the lead responsibility for the advisory body. The executive secretary provides guidance to the secretariat and reports back to advisory bodies on how Health Canada used their advice.
External advisory body	<ul> <li>These are the defining characteristics of an external advisory body:</li> <li>it is established by the Minister(s) or the Department to provide advice on specific medical, scientific, technical, policy, or program matters within the scope of Health Canada's mandate;</li> <li>its members are external to the federal government and are selected to provide Health Canada with expert advice; and</li> <li>it provides its advice to Health Canada as a group and not as individuals or representatives of organizations.</li> <li>Health Canada may collaborate with another government department, agency, or organization to convene or support the work of an external advisory body. Health Canada retains its decisionmaking authority and decides how it will use the recommendations and advice of an external advisory body.</li> </ul>

Honorarium	An honorarium is a voluntary payment made to an individual who is not a government employee in situations where payment is not legally required or expected. Honorariums are not meant to be used frequently or as a mechanism to deliver a program, particularly on an ongoing basis. Examples of honorariums are tokens of appreciation for volunteer speakers or when engaging in consultations with Indigenous groups.
	Honorariums are not an appropriate mechanism to procure services. In general, honorarium payments are issued by departments to show appreciation. They have low individual value and can be issued in a monetary form or as goods. When they are issued as goods, special authorities must be sought in advance of payment. When they are issued in a monetary form, they may be issued under a transfer payment program or as an ex gratia payment.
	In summary, honorariums:
	do not represent a service contract;
	<ul> <li>are not an entitlement, as there is no expectation of payment in exchange for the service rendered; and</li> </ul>
	<ul> <li>are not recurring payments to the same individual.</li> </ul>
Public	All individuals and groups who may be interested in or affected by the advice provided by an advisory body. The definition does not require the certainty that any individual or group has such an interest, just that they may have an interest. Therefore, the public includes consumers, patients, professionals and members of academia and industry and the groups that represent them.
Secretariat	A dedicated resource that provides organizational and administrative support to an advisory body. A secretariat is composed of Health Canada officials and may be supported by a working group within Health Canada.
Vice-Chair	The person appointed to act on behalf of the chair in case of the chair's absence or at the request of the chair.

