



# Formulary Management Expert Committee (Interim)

## Terms of Reference

### 1.0 Mandate

The Formulary Management Expert Committee (FMEC) is an interim committee introduced as a pilot in fiscal year 2023–2024. A pilot format provides the agility needed to test and learn from innovative approaches to reviews, methods, deliberative processes, stakeholder inputs, and the communication of outputs.

FMEC provides recommendations for the organization's nonsponsored single drug reviews, streamlined drug class reviews, and therapeutic reviews as requested by federal, provincial, and territorial governments; drug plans; and cancer agencies. These recommendations are intended to increase the likelihood that reviews across the pharmaceutical life cycle will result in system impact.

### 2.0 Roles and Responsibilities

The responsibilities of FMEC (herein referred to as "the committee") include:

- producing recommendations for the organization's reviews, including, but not limited to, nonsponsored single drug reviews, streamlined class reviews, and therapeutic reviews
- using the organization's reviews and input from stakeholders (i.e., patient representatives, clinical experts, and pharmaceutical manufacturers) to develop recommendations as to whether certain pharmaceutical products should be reimbursed, and the conditions for reimbursement
- using the organization's reviews and input from stakeholders (i.e., patient representatives, clinical experts, and pharmaceutical manufacturers) to develop recommendations as to what reimbursement or other policies would promote the optimal use of certain pharmaceutical products in Canada
- providing guidance to the organization and participating federal, provincial, and territorial ministries of health, as requested, on other issues related to reimbursement and the optimal use of pharmaceutical products across the life cycle.

### 3.0 Authority

The committee shall report to the President and CEO through its Chair.

### 4.0 Membership

The committee is composed of 9 core members, as follows:

- 1 Chair



- 1 patient member representative
- 1 health economist
- 6 expert members who hold qualifications as physicians, pharmacists, or other professional health designations, and have expertise and experience in 1 or more of the following areas: health economics, health policy or administration, pharmacy, clinical pharmacology, general medical practice, internal medicine, and any other recognized medical specialty.

Members are expected to have experience and knowledge related to health technology assessment, reimbursement policy, and/or epidemiology.

In addition to its core members, the committee will engage up to 2 specialist members. Specialist members will be selected on their expertise with respect to the specific project and therapeutic area under deliberation. Specialist members are expected to have familiarity with the pharmaceutical product(s) under review through their clinical activities, research, and/or experience in health policy, health care administration, or other health-related work.

#### **4.1 Appointment Process**

Core members shall be appointed by the President and CEO.

Specialist members shall be appointed by either the Executive Vice-President, Evidence, Products, and Services or the Director, Pharmaceutical Policy and HTA.

#### **4.2 Removal**

Notwithstanding anything set out in these terms of reference, the President and CEO shall have the right to remove and/or replace a committee member at or before the expiry date of their term.

#### **4.3 Resignation**

A member may resign by providing the Chair and President and CEO with a written resignation; such resignation becomes effective when received by the organization, at the time specified in the resignation, or at a mutually agreed to time.

### **5.0 Term of Appointment**

#### **5.1 Core Members**

Core committee members shall be appointed for a term that coincides with the anticipated duration of the pilot process, but the term may be extended at the discretion of the President and CEO to support continuity.

Participation as a core member in the FMEC pilot will not be included in calculations of the maximum term of service, should the committee transition to a standing body.



## 5.2 Specialist Members

Specialist members will be selected on their expertise and appointed for the duration of a specific project under deliberation.

## 6.0 Officers

The officer of the committee is the Chair.

### 6.1 Appointment Process

One member shall be appointed by the President and CEO to serve as Chair of the committee.

### 6.2 Term

Officers shall ordinarily hold office for a term that coincides with the anticipated duration of the pilot process, but the term may be extended at the discretion of the President and CEO to support continuity.

### 6.3 Powers and Duties

The Chair shall, when present, preside at all meetings of the committee. The Chair shall act as the committee spokesperson when requested to do so by the President and CEO. Per sections 7.3 and 13.0, the Chair shall participate in the development of meeting agendas and report on committee activities to the Board of Directors.

## 7.0 Meetings

The committee will typically meet on a bimonthly cadence, scheduled to best accommodate core and specialist member availability. Additional meetings may be called at the discretion of the organization.

### 7.1 Attendance

Members shall make best efforts to attend all meetings of the committee. Alternates are not permitted to attend in place of a member.

### 7.2 Quorum

The appointed specialist member(s) for the specific project under deliberation and a majority (50% plus 1) of incumbent voting core members shall constitute quorum.

### 7.3 Agenda

Meeting agendas are prepared by the organization in consultation with the committee Chair.



## 7.4 Decision-Making

Committee decisions shall be made by a majority vote of the core members in attendance.

Each core member shall be entitled to 1 vote. The Chair of the meeting shall not normally vote except in the event of a tie, in which case the Chair of the meeting may exercise a casting vote. All committee members must support the decisions of the committee.

### 7.4.1 Abstaining

Although full participation of members is in the best interests of the work undertaken by the committee and the organization, in some cases core members may abstain from voting. If a core member is not present for the majority of the discussion on the motion being passed, or if the core member has a conflict of interest, the member will abstain from voting.

When a core member abstains, their vote is not counted and the decision is made by a majority of the remaining voting members.

## 7.5 Minutes

The organization's staff keep a written record of committee meetings. A copy of the minutes will be provided to each committee member.

## 7.6 Attendees

In addition to committee members and observers invited in accordance with section 7.7, only the following persons shall be entitled to attend committee meetings:

- members of the Pharmaceutical Advisory Committee (PAC), the Provincial Advisory Group (PAG), and the Formulary Working Group (FWG)
- members of the participating public drug plans
- representatives of Health Canada
- members of the pan-Canadian Pharmaceutical Alliance (pCPA)
- advisors designated by the organization
- the organization's staff (as subsequently noted).

At each meeting, attending PAC, PAG, and/or FWG members will be given the opportunity to provide their perspective on the submission(s) for consideration by the committee. These attendees shall not have the right to participate in committee deliberations (i.e., beyond the steps of information gathering and clarification) or to vote.

The organization's staff attending the meeting shall serve as a resource to the committee. The staff provides administrative and secretariat support and may actively participate in the presentation of information at the request of the Chair. The staff shall also assist in obtaining additional information and/or expert advice at the committee's request.



Notwithstanding the previously outlined policies, as part of a pilot process, the organization reserves the right to test different approaches to committee meetings, which may include, but are not limited to, inviting other partners and collaborators to observe meetings, consistent with its guiding principles of transparency and partnership.

## **7.7 Observers and Guests**

The organization, in consultation with the Chair, may invite observer(s) and guest(s) to attend committee meetings from time to time. To maintain the confidentiality of committee discussions and information, invited observers and guests are required to sign a nondisclosure agreement before attending a committee meeting.

Observers typically represent external organizations, partners, or collaborators who have an interest in the committee's work. The role of an observer is limited to attending meetings to observe the proceedings. Observers are not permitted to actively participate in committee discussions or decision-making processes.

Guests are individuals who are invited to provide expertise or perspectives on a particular committee agenda item. Guests may participate in discussions related to their area of expertise, but do not hold a continuous role on the committee. Guests do not participate in committee decision-making processes.

The committee shall have the right to exclude observers and guests from any meeting held in camera, either in whole or in part.

## **8.0 Code of Conduct**

All committee members shall comply with the organization's code of conduct.

## **9.0 Conflict of Interest**

All committee members shall comply with the organization's conflict of interest policy. Conflicts of interest shall be declared at the start of each meeting.

## **10.0 Indemnification**

Every committee member shall be indemnified and saved harmless by the organization from and against:

- all costs, charges, and expenses that such committee member sustains or incurs in or about any action and suit of proceedings that is brought, commenced, or prosecuted against them, or in respect of any act, deed, matter, or thing, whatsoever, made, done, or permitted by them in or about the execution of the duties of such committee members or in respect of any such liability
- all such costs, charges, and expenses that such committee member sustains or incurs in or about in relation to the affairs thereof, except such costs, charges, or expenses as are occasioned by their own wilful neglect or default.



## **11.0 Confidentiality**

It is the responsibility of committee members to know what information is confidential and to obtain clarification from the organization when in doubt. Except as compelled by the applicable legal process, a committee member must, both while having and after ceasing to have that status, treat as confidential all information regarding the policies, internal operations, systems, business, or affairs of the committee and of the organization obtained by reason of their status as a committee member and not generally available to the public. A committee member shall not use information obtained as a result of their involvement on the committee for personal benefit. Each committee member shall avoid activities that may create the appearance that they have benefited from confidential information received during the course of their duties as a committee member.

Additional information on confidentiality is reflected in the organization's code of conduct (available on the organization's website).

## **12.0 Remuneration**

Upon appointment, members will be eligible to receive remuneration based on a set number of hours allocated for deliberations and meetings. Remuneration will be paid to the individual and is subject to deductions for Canada Pension Plan (CPP) and income taxes.

Expenses incurred while performing duties as a committee member are eligible for reimbursement in accordance with the organization's travel policy.

## **13.0 Reporting**

The committee shall make a report to the Board of Directors at least annually through its Chair by verbal and/or written means.

## **14.0 Secretariat Support**

Secretariat support for the committee shall be provided by the organization's staff.

## **15.0 Amendments to the Terms of Reference**

These terms of reference may be amended at any time at the discretion of the President and CEO.