Scientific Advisory Committee on Pharmaceutical Sciences and Clinical Pharmacology (SAC-PSCP)

Terms of Reference

The Scientific Advisory Committee (SAC) on Pharmaceutical Sciences and Clinical Pharmacology (SAC-PSCP) provides advice to Health Canada on pharmaceutical science and clinical pharmacology issues. The Committee provides Health Canada with advice and recommendations, but the decision-making responsibility remains with Health Canada.

These Terms of Reference for the SAC-PSCP were accepted on June 26, 2012.

1. Mandate

The Scientific Advisory Committee on Pharmaceutical Sciences and Clinical Pharmacology will provide Health Canada with timely scientific, technical and clinical advice on pharmaceutical science and clinical pharmacology issues affecting data requirements for new formulations of drugs, for example, pharmaceutical equivalence for generic drug products, new salts, complex formulations, etc.

2. Reporting Structure

The Committee reports to the Director General (DG), Therapeutic Product Directorate (TPD), who acts as the Executive Secretary to the Committee. The TPD will provide support to the Committee, as appropriate.

3. Membership

3.1 Selection of members

Members of the SAC-PSCP are recruited through open and targeted nomination processes. Members are identified from a broad array of sources such as health professional and scientific societies; academia; government and non-government agencies and/or the public. Occasionally, the Chair consults with Health Canada employees regarding the selection of candidates from previous scientific advisory bodies. In order to preserve the independence of both the advisory body and the federal government as decision-maker, Health Canada employees may not serve as members of the SAC-PSCP.

This process is designed to ensure requisite expertise and experience, and a variety of perspectives, promoting diversity and inclusiveness.

The Executive Secretary selects and appoints a Chair and members from among the nominees.
Membership of the Committee as a whole will reflect an appropriate blend of gender and regional representation, covering various areas of expertise, knowledge, and perspectives including health professionals, scientists, and academia. Member’s expertise should include, but is not limited to areas such as:

- bioequivalence;
- biostatistics;
- pharmacology;
- laboratory analytical techniques;
- medicinal chemistry;
- medicine;
- pharmacy;
- pharmaceutical manufacturing;
- pharmaceutical product formulation;
- pharmacokinetics; and
- physical pharmacy.

3.2 Types of Members

The Committee has two types of members, core and ad hoc members, selected for their scientific, technical and clinical expertise and knowledge. Core members are permanent members for the duration of their terms. Ad hoc members are invited to serve for a specific topic or group of topics.

3.3 Tenure

Members are appointed by the Executive Secretary for a two-year term which may be extended for an additional two or four year term up to a maximum of eight years. The Secretariat will review membership on a regular basis in consultation with the Chair, and will make recommendations to the Executive Secretary. The Secretariat will endeavour to ensure that appointments of members are scheduled to allow for continuity and systematic rotation of membership.

3.4 Size of the Committee

The SAC-PSCP has at least ten core members, not to exceed fifteen. Membership may be periodically adjusted to ensure the appropriate representation of expertise and experience.

3.5 Security Clearance

All members are required to undergo a security clearance to the level of “reliability status”. Sometimes, but not often, this may entail taking a member’s fingerprints should the Royal Canadian Mounted Police require them. A security clearance is valid for ten years.
3.6 Affiliations and Interests

As a condition of appointment, potential members of the SAC-PSCP are required to complete and return the “Affiliations and Interests Declaration Form for Advisory Body Members.” This form is used to disclose to the Secretariat (TPD) any circumstances that may place, or be seen to place the member in a real, apparent, or potential conflict of interest.

In keeping with the Privacy Act, this completed Affiliations and Interests Declaration Form is considered confidential. The TPD will not make public any information in the form without the member’s permission. However, as a condition of membership, members will allow the TPD to publish on Health Canada’s website a “Summary of Expertise, Experience, and Affiliations and Interests,” which will be based on the completed Declaration Form. Members will be asked to review the content of the Summary for accuracy before its release.

It is incumbent upon the member to update his/her declaration in writing, should his/her personal situation change or where the matters before the Committee may affect the conflict of interest situation of a member. Declarations will be assessed by the TPD prior to appointment and on an ongoing basis as updates occur.

At the beginning of the meeting, the Executive Secretary or the Chair will ask members to make a verbal statement of their relevant affiliations and interests. The level of participation of a member in conflict is determined by the Chair in consultation with the other members of the Committee.

Members are expected to conduct themselves in an appropriate manner, that is [i.e.], the use of their positions cannot be reasonably construed to be for their private gain or that of any other person, company, or organization.

All members are expected to protect and maintain as confidential any trade secret or privileged information divulged during the work of the Committee. Members must not discuss this information with persons not on the Committee, or divulge information obtained from the work of the Committee, including presentations made to it, until such time as this information has been officially released for public distribution. Documents leaving Health Canada, including electronic and word processing records must be securely stored at all times and must be returned to Health Canada or permanently deleted on request.

3.7 Indemnification and Legal Assistance

All members serve on the SAC-PSCP on a volunteer basis. In keeping with the Treasury Board’s “Policy on Legal Assistance and Indemnification”, 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 SAC-PSCP and serving as volunteers.
3.8 **Travel and Expenses**

Members are reimbursed for expenses incurred during their work on the SAC-PSCP such as travel and accommodation, according to the Treasury Board’s “*Travel Directive and Hospitality Policy.*”

3.9 **Resignation from the Committee**

An individual may withdraw from service on the SAC-PSCP at any time upon fourteen days written notice to the Secretariat. The letter should state the effective date of resignation.

3.10 **Reasons for termination**

Core members who are absent from three consecutive meetings of the SAC-PSCP will forfeit membership in the Committee. *Ad hoc* members who do not attend in response to two consecutive invitations will forfeit membership in the Committee. Generally, a member’s failure to act according to the Terms of Reference may give cause for termination. In this event, the Executive Secretary will advise the member in writing, stating the reason for the termination and the effective date.

4. **Roles and Responsibilities**

4.1 **Members**

Members of the SAC-PSCP have a responsibility to Health Canada and by extension to Canadians, to offer their independent and objective advice. Other responsibilities include:

- being available and prepared to participate in the meeting;
- participating in any discussions surrounding the preparation of meeting reports, if necessary;
- notifying the Secretariat and the Chair of any changes in the status of their affiliations and interests of relevance to the mandate; and
- making a verbal statement of affiliations and interests at the beginning of each meeting when asked by the Executive Secretary or the Chair.

4.2 **Chair (Vice-Chair)**

In addition to all the responsibilities of a member, the Chair or Vice-Chair is responsible for the following:

- providing input to and consulting with the Executive Secretary on the selection of members;
- consulting with the Executive Secretary to determine whether to limit the participation of a member in the meeting, depending on the nature of the person’s affiliations or interests;
- overseeing and chairing the meeting, and facilitating discussion among members in answering the TPD’s questions;
• ensuring that all members agree with, or note their disagreement with, the advice in the report to the TPD.

4.3 Secretariat

The Office of Science of the TPD acts as the Secretariat of the SAC-PSCP. The Secretariat liaises between members and the Health Canada, and acts as a resource for members. It also provides leadership and strategic advice in the management of the SAC-PSCP and works closely with the Chair. In addition, the Secretariat:

• coordinates membership processes such as the affiliations and interests declarations, security clearances, and a membership list;
• coordinates the preparation of the meeting agenda, prepares background information packages for the SAC-PSCP and marks it according to the level to which it is protected under the “Government Security Policy,” and drafts the record of proceedings for the members and the Chair’s approval;
• maintains any information about the SAC-PSCP, its mandate, or work that may be posted on Health Canada’s website;
• helps to prepare the member designated as media spokesperson, as appropriate;
• coordinates requests for travel reimbursement;
• monitors and evaluates the efficiency and effectiveness of the SAC-PSCP;
• carries out additional duties as appropriate in support of the SAC-PSCP; and
• reports back to the members as to how their advice has been used by Health Canada.

4.4 Executive Secretary

The Executive Secretary is the Director General (TPD) who represents Health Canada and makes decisions about the SAC-PSCP and its advice. The Executive Secretary provides leadership and strategic advice in the management of the SAC-PSCP and works closely with the Chair and Secretariat.

4.5 Media and Communications

All members are expected to protect and maintain as confidential any trade secret or privileged information divulged during the work of the Committee. Discussion of SAC-PSCP work with the media or at conferences or other external events should only be done when authorization is given by the Executive Secretary.

In the case of media requests, the Executive Secretary, will coordinate a response in consultation with the Chair and the Health Canada Media Relations and will appoint a member to be the media spokesperson when circumstances warrant this.
5. Management and Administration

5.1 Transparency

Health Canada is committed to ensuring transparency as an operating principle by:

- ensuring that the meeting schedule is appropriate; and
- posting SAC-PS materials, with confidential and personal information removed, on Health Canada’s website including:
  - Terms of Reference;
  - Membership;
  - Summary of Member’s Expertise, Experience, and Affiliations and Interests;
  - Biographies of members;
  - Agenda;
  - Record of Proceedings and/or formal reports and Health Canada’s response.

5.2 Meeting agenda

The agenda and specific questions and issues for SAC-PSCP discussions will be determined by the Executive Secretary in consultation with the Chair and the Secretariat.

5.3 Meeting notice and Invitation

This meeting is held at the call of the Executive Secretary in consultation with the Chair. Meeting attendance is by invitation only. The notice is sent by the Secretariat. Members receive the agenda, briefing material and presentations, in advance of the meeting.

5.4 Frequency, Type, and Location of meeting

This meeting will be held in the National Capital Region. Rarely, an additional teleconference may be held on a needs basis at the discretion of the Executive Secretary in consultation with the Secretariat. A meeting cannot be held unless quorum is achieved. The quorum is determined to be at least one-half the number of existing core members, one of which must be the Chair.

For all teleconferences, members should make every effort to ensure that a secure line is used for the call and that no person who has not been approved by the Chair and Secretariat can listen to the proceedings.

The SAC-PSCP may be required to hold a meeting, or parts of a meeting, in public to allow the public to observe the discussions and understand the issues under consideration.
5.5 Deliberations and Reports

Deliberations during the meeting are held in camera in order to foster open, frank, and free-flowing discussion. All members have equal status during discussion, and are expected to demonstrate fairness and a commitment to in-depth examination of matters under review. Only topics that fit within the mandate of the SAC-PSCP will be discussed.

At the discretion of the Executive Secretary and with the approval of the Chair, specific stakeholders may be invited to make presentations to the Committee in writing or in person. The Chair and the Executive Secretary may grant observer status, for all or part of the Committee deliberations to selected individuals, including Health Canada employees who would benefit from the deliberations of the Committee.

Members provide advice to Health Canada in the form of recommendations. These recommendations are captured in a record of proceedings (RoP). The SAC-PSCP is encouraged to reach a consensus in providing advice whenever possible. When a consensus is not possible, the RoP will reflect the diversity of opinions. The reasons for a lack of consensus, if any, must be clearly identified and substantiated. In such cases, the SAC-PSCP shall make a recommendation with respect to further study of the issue and a proposal for resolution. In cases where there is a real divergence of opinion, the different opinions will be documented, and the number of members supporting each opinion recorded.

A draft RoP is prepared by the Secretariat and circulated to members for review, and final approval by the Chair and Executive Secretary. The final RoP will effectively summarize the proceedings to reflect the advice offered and there will be no attribution, i.e. there will be no references to comments made by individual members or the public. The Secretariat is responsible for the distribution of the RoP.

The agenda and the record of proceedings will be posted on Health Canada’s website in both official languages. Issues discussed on a particular submission are considered confidential and the meeting documents will become part of the Central Registry file. In the event that the Chair and the Executive Secretary believe that the SAC-PSCP would benefit from broader stakeholder input, a portion of the meeting could become public.

5.6 Review

The Secretariat will initiate an evaluation of the SAC-PSCP every two years, and will work with the Executive Secretary and the Chair to review the mandate, activities, Terms of Reference, and relevance of the SAC-PSCP to ensure that it continues to meet ongoing needs. The TPD retains the prerogative to disband the committee following such a review. Recommendations for improvement will be considered on an ongoing basis.
6. References

The Health Products and Food Branch’s “Guidance on Advisory Bodies,” and “Policy on Public Input” govern the Terms of Reference, and the management and administration of the SAC-PSCP. These documents are available electronically at:
