Health Canada Santé Canada

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SCIENTIFIC ADVISORY COMMITTEE ON BIOAVAILABILITY AND BIOEQUIVALENCE

TERMS OF REFERENCE

The Scientific Advisory Committee (SAC) on Bioavailability and Bioequivalence (BB) acts as a forum of advice and a sounding board for management and scientists of Health Canada (HC) . The SAC will primarily be consulted in areas of bioavailability of drugs, pharmacokinetics and bioequivalence issues, but the decision-making responsibility remains with HC.

1. MANDATE

To provide on-going and timely scientific, medical and clinical advice on current and emerging issues related to the work of HC pertaining to bioavailability and bioequivalence of drugs.

The Committee fulfils its mandate by advising on specific questions raised by HC. Questions will be related to the bioavailability of drugs, including both pharmaceuticals and biologicals, and will focus primarily on reviewing information brought to the Committee by HC in order to provide guidance, and formulate new guidance documents. Issues for committee consideration could include:

- guidances for sponsors of New Drug Submissions and Abbreviated New Drug Submissions;
- issues such as bioavailability of new active substances, or topics relating to bioavailability such as interactions with drugs, foods, natural health products or environmental contaminants;
- new approaches to assessing bioequivalence dealing with population and individual bioequivalence to account for factors such as gender and age, and their effect on bioavailability;
- expertise will also be sought for developing guidances in situations when the usual bioavailability measure may not be appropriate, or when reduced clinical requirements can be considered;
- issues arising from a wide range of product types, such as modified-release formulations, metered dose inhalers and other more complicated release mechanisms/delivery systems.
- the development of ‘standards of evidence’ for risk and benefit decision-making for BB studies;
- issues arising directly from sponsor’s drug submissions;
- issues arising from post-market surveillance activities;
- labelling, product monographs, package inserts and warnings;
- advice during emergency situations.

The Committee explores options and provides recommendations for resolution of the issue(s).

2. REPORTING STRUCTURE

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

3. MEMBERSHIP / PARTICIPATION / QUALIFICATIONS

a) Types of Members - The Committee has two types of members, core and *ad hoc* members, selected for their 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 for a defined term.

b) Size of the Committee - The number of core members will not exceed 11 people. In order to remain effective and efficient, the Committee should not exceed 18 members for any meeting.

c) Selection of Members - The DG selects and appoints a Chair and an Associate Chair from among the existing core members or nominees. In the absence of the Chair, or in any other circumstance where the Chair cannot effectively perform his/her duties, the Associate Chair will lead the Committee.

Core and *ad hoc* members are selected by the DG in consultation with the Chair. Potential core and *ad hoc* members are identified through consultation with a broad array of sources (for example: health professional and scientific societies; academia; government agencies).

The membership of the Committee as a whole will reflect an appropriate blend of gender and regional representation, covering various areas of expertise and knowledge such as:

- pharmacokinetics including bioavailability & bioequivalence requirements
- biostatistics
- primary care management, specialty and subspecialty areas in medicine
- basic and applied pharmaceutical/biological sciences and technologies
- public interest needs

Since core and *ad hoc* members are appointed as individuals on the basis of their individual expertise, they will not represent their firms, organizations or affiliations directly. They serve on the Committee as knowledgeable individuals in their own right and in the best interests of all Canadians, aiming to promote optimal pharmacotherapy through their advice, while recognizing the roles and responsibilities of patients, and health professionals in achieving this goal.

Health Canada staff may not serve as members of the Committee. The TPD staff provides Secretariat support, responds to questions and provides information at the call of the Chair.

At the discretion of the Executive Secretary and in consultation with the Chair, interested parties or concerned members of the public may be invited to make representations to the Committee in writing or in person, or may be granted observer status.

4. PROPOSED TENURE / LIFE CYCLE

a) Term - The Chair is normally appointed for a two-year term. A single extension to the individual's term of office may be considered.

Core members are normally appointed for a minimum term of two years. They may be reappointed for further two or four year terms, to a maximum of eight years.

Ad hoc members are appointed for specific meetings or for specific subjects in which they have expertise, for a term up to three years. They may be reappointed for a further term to a maximum of two consecutive terms. Invitations to attend meetings are issued in writing.

The Director General will endeavour to ensure that appointments of core and *ad hoc* members are scheduled to allow for continuity and systematic rotation of membership.

b) Forfeiture of Membership - Core members who are absent from three consecutive meetings of the Committee 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.

c) Withdrawal from Committee - An individual may withdraw from membership on the Committee at any time upon written notification to the Executive Secretary. Membership may be terminated at any time upon written notification from the Executive Secretary.

5. SECURITY CLEARANCE, CONDUCT AND CONFLICT OF INTEREST

All Committee members are subject to a security clearance to the level of "enhanced reliability". Sometimes, but not often, this may entail the taking of member's finger-prints should the RCMP require them. Security clearance is valid for ten years.

Documents leaving HC, including electronic and word processing records must be securely stored at all times and must be returned to HC or permanently deleted on request.

Committee members are expected to conduct themselves in an appropriate manner, i.e. the use of their positions cannot be reasonably construed to be for their private gain, or that of any other persons or organization. They must refrain from any conflict of interest and, indeed, its very appearance. In situations where conflict of interest, or the appearance thereof arises in the course of the work of the Committee, the individual involved must declare its existence and disqualify himself/herself from participation in the discussion and/or from further membership on the Committee according to the circumstances or specific situation.

Guidance on conflict of interest is provided to potential members when discussing the appointment. Before appointment, all potential Committee members are required to submit conflict of interest declarations to disclose to HC any circumstance that may place, or be seen to place the member in a real, apparent or potential conflict of interest. It is incumbent upon the member to update his / her disclosure should his / her personal situation change.

Prior to each meeting the Committee Co-ordinator shall conduct a conflict of interest review specific to the subject(s) at hand. The level of participation of a member in conflict is determined by the Chair in consultation with the other members of the Committee.

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 after the information in question has been officially released for public distribution. Discussion of Committee work with the media or at conferences should only be done when authorization is given by the DG-TPD in consultation with the Chair.

6. INDEMNIFICATION OF AND LEGAL ASSISTANCE

Members who "volunteer"(i.e., do not receive an honorarium) are covered under Treasury Board's "Volunteer Policy" and automatically receive indemnification and legal assistance. Members who receive an honorarium are appointed by the Deputy Minister and are thus protected as Departmental appointees for purposes of indemnification and legal assistance.
Members are only protected when the advice given lies within the mandate of the Committee.

7. COMPENSATION

Members are compensated for travel expenses according to federal government policy. Honoraria may be paid to persons outside the Government of Canada for the performance of a service that is not normally covered by other forms of compensation such as salary, wages or fees. The *per diem* rate for honoraria is set by HC. Specific contractual arrangements will be made should additional work be offered or assigned to committee members.

8. MANAGEMENT AND ADMINISTRATION

The specific questions and issues for Committee discussion are determined by the Executive Secretary in conjunction with the Chair with input from HC staff, Committee members and stakeholders. The agenda is developed by the Executive Secretary of the Committee in collaboration with the Chair.

Invitations to attend a meeting are sent out by the Secretariat of the Committee. Members receive the agenda, briefing materials and other documentation in advance of meetings. When issues are of a general nature, the agenda will be posted on HC website along with the record of proceedings once approved by the Chair. Issues discussed on a particular submission are confidential and the record of proceedings will become part of the Central Registry file. If the Chair and DG believe that the Committee would benefit from broader stakeholder input, a portion of the meeting could become public.

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

The SAC- BB is supported by a Working Group (WG) composed of members from selected bureaux of HC. The WG functions to identify and prioritize potential issues for review, reviews the issues and develops possible approaches to their resolution, identifies resources available within HC, and prepares information that would be useful to the Committee, ensures that the Committee receives a fair and balanced information package and presents current policy interpretations and operational processes to the Committee.

Meetings are held at the call of the Director General in collaboration with the Chair, and are held in the National Capital Region, or by video-conference or teleconference if the need arises. The member should make every effort to ensure that a secure line is used for teleconferences and that no person not approved by the Chair can listen to the proceedings. There will usually be two scheduled meetings each year, with additional meetings if necessary.

A quorum shall consist of at least one half the number of existing core members, one of which must be the Chair or Associate Chair.

Discussion during meetings shall be open, frank and free-flowing. All members of the Committee will have equal status during discussion. In cases where the information to be discussed is confidential, discussions will be held *in camera*. Committee members are expected to demonstrate fairness and a commitment to in-depth examination of matters under review. Topics that do not fit within the mandate of the Committee will not be discussed. They should be referred to HC, or the Committee should request a change in its mandate.

Committee members review the information provided by the Secretariat and provide advice on the specific questions brought before them by HC. Members might be asked to identify issues, conduct research, or to seek counsel from others as required, with due regard for the confidentiality of the information and budgetary constraints. From time to time, members may be asked to comment on written drafts pertaining to the subjects within the mandate of the Committee.

Advice from the Committee is in the form of recommendations to the DG of TPD, and they are reached by consensus. Lack of consensus may indicate uncertainty of information. The reasons for lack of consensus, if any, must be clearly identified and substantiated. In such cases, the Committee 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.

Records of Proceedings of the meeting are prepared after the meeting by the Secretariat and will be approved by the Chair in consultation with the core and *ad hoc* members present for the meeting. Records of Proceedings are kept to the minimum detail required to summarize effectively the proceedings and to accurately reflect the decisions taken. There is no attribution. There is no other record of meetings. The Secretariat is responsible for the distribution of the records of proceedings. They are made available to stakeholders at the discretion of the Director General and are subject to Access to Information and Privacy legislation. Since the records of proceedings of the committee meetings are disclosable, confidential third party information or confidential information obtained from other governments should be attached as an appendix, and must be clearly identified and marked as confidential.

The TPD reviews the Committee every two years to ensure that the Committee continues to meet HC's on-going needs. The Directorate retains the prerogative to disband the Committee following such review.