Health Canada Santé Canada

Scientific Advisory Panel on Bioequivalence Requirements for Modified-Release Dosage Forms (SAP-MRDF)

Draft Terms of Reference

The Scientific Advisory Panel (SAP) on Bioequivalence Requirements for Modified-Release Dosage Forms (SAP-MRDF) provides advice to Health Canada on appropriate bioequivalence standards for modified-release dosage forms of pharmaceutical drugs. Of particular interest are those drugs where concerns have been raised that existing standards may not be adequate, for example, methylphenidate and nifedipine. The Panel provides Health Canada with advice and recommendations, but the decision-making responsibility remains with Health Canada.

These Terms of Reference for the SAP-MRDF were accepted on [*date*].

1. MANDATE

To provide timely scientific, medical and clinical advice on appropriate bioequivalence standards for modified-release dosage forms of pharmaceutical drugs. Of particular interest are those drugs where concerns have been raised that existing standards may not be adequate, for example, methylphenidate and nifedipine. The Panel fulfils its mandate by advising on specific questions raised by Health Canada.

2. REPORTING STRUCTURE

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

3. MEMBERSHIP

3.1 Selection of members

Members of the SAP-MRDF are selected 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 SAP-MRDF.

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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 Panel 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, academia, and lay representation. Members should include, but are not limited to areas such as:

- pharmacokinetics;
- cardiology;
- psychiatry.

3.2 Types of Members
The Panel members are selected for their scientific/medical/technical expertise and knowledge.

3.3 Size of the Panel
The SAP-MRDF has at least 6 members (5 and a chair) to ensure the appropriate representation of expertise and experience.

3.4 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.

3.5 Affiliations and Interests
As a condition of appointment, potential members of the SAP-MRDF 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 Panel 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 Panel.

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 Panel. Members must not discuss this information with persons not on the Panel, or divulge information obtained from the work of the Panel, 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.

3.6 Indemnification and Legal Assistance

All members serve on the SAP-MRDF on a volunteer basis. In keeping with the Treasury Board's "*Policy on Indemnification of and Legal Assistance for Crown Servants*" and *"Volunteer Policy,"* 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 SAP-MRDF and serving as volunteers.

3.7 Travel and Expenses

Members are reimbursed for expenses incurred during their work on the SAP-MRDF such as travel and accommodation, according to the Treasury Board's "*Travel Directive and Hospitality Policy*."

4.0 ROLES AND RESPONSIBILITIES

4.1 Members

Members of the SAP-MRDF 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 in relevance to the mandate; and
- making a verbal statement of affiliations and interests at the beginning of the meeting when asked by the Executive Secretary or the Chair.

4.2 Chair

In addition to all the responsibilities of a member, the 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 SAP-MRDF. The Secretariat liaises between members and Health Canada, and acts as a resource for members. It also provides leadership and strategic advice in the management of the SAP-MRDF 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 SAP-MRDF 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 SAP-MRDF, 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 SAP-MRDF; and
- carries out additional duties as appropriate in support of the SAP-MRDF.

4.4 Executive Secretary
The Executive Secretary is the Director General (TPD) who represents Health Canada and makes decisions about the SAP-MRDF and its advice. The Executive Secretary provides leadership and strategic advice in the management of the SAP-MRDF 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 Panel. Discussion of SAP-MRDF 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 Health Canada Media Relations and will appoint a member to be the media spokesperson when circumstances warrant this.

5.0 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 SAP-MRDF materials, with confidential and personal information removed, on Health Canada's website including:
    - Terms of Reference;
    - Membership;

- Summary of 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 SAP-MRDF 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 SAP-MRDF 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 SAP-MRDF 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 Panel in writing or in person. The Chair and the Executive Secretary may grant observer status, for all or part of the Panel deliberations to selected individuals, including Health Canada employees who would benefit from the deliberations of the Panel.

Members provide advice to Health Canada in the form of recommendations. These recommendations are captured in a record of proceedings (RoP). The SAP-MRDF 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 SAP-MRDF 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 SAP-MRDF would benefit from broader stakeholder input, a portion of the meeting could become public.

6.0 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 SAP-MRDF. These documents are available electronically at:

http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/public-rev-exam/advisory-consultatif-eng.php, and

http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/public-rev-exam/rev_reg_prod-exa-eng.php.