

# Scientific Advisory Panel on Bioequivalence Requirements for Gender-Specific Drug Products (SAP-GSDP)

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## Terms of Reference

The Scientific Advisory Panel (SAP) on Bioequivalence Requirements for Gender-Specific Drug Products (SAP-GSDP) provides advice to Health Canada on appropriate bioequivalence study requirements for pharmaceutical drug products intended for administration either only to females or only to males. Of particular interest are those drug products where concerns have been raised that existing study requirements may not be adequate, for example, combination products containing pyridoxine and vitamin B6 for the treatment nausea in pregnancy. The Panel will provide Health Canada with advice and recommendations, but the decision-making responsibility remains with Health Canada.

These Terms of Reference for the SAP-GSDP were accepted on June 2, 2011.

### 1.0 MANDATE

The mandate of the SAP-GSDP is to provide timely scientific, medical and clinical advice on appropriate bioequivalence study requirements for pharmaceutical drug products intended for administration either only to females or only to males. Of particular interest are those drug products where concerns have been raised that existing study requirements may not be adequate, for example, combination products containing pyridoxine and vitamin B6 for the treatment nausea in pregnancy. The Panel fulfils its mandate by advising on specific questions raised by Health Canada.

### 2.0 REPORTING STRUCTURE

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

### 3.0 MEMBERSHIP / PARTICIPATION / QUALIFICATIONS

#### 3.1 Selection of members

Potential members of the SAP-GSDP are selected from a broad array of sources such as health professionals and scientific societies, academia, and government agencies. 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-GSDP.

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 from among the existing members or nominees whereas other members may be selected by the Executive Secretary in consultation with the Chair.

Membership of the SAP-GSDP 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:

- pharmacokinetics
- obstetrics;
- pharmacology

### **3.2 Types of Members**

The Panel members are selected for their scientific/medical/technical expertise and knowledge.

### **3.3 Tenure**

Members are appointed by the Executive Secretary for a single teleconference. If necessary, a second teleconference and/or meeting may be organised.

### **3.4 Size of the Panel**

The SAP-GSDP will be comprised of no more than seven (six members plus one Chair).

### **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 & Interests**

As a condition of appointment, potential members of the SAP-GSDP 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 with potential 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.

### **3.7 Indemnification and Legal Assistance**

All members serve on the SAP-GSDP 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 SAP-GSDP and serving as volunteers.

### **3.8 Travel and Expenses**

Members are reimbursed for expenses incurred during their work on the SAP-GSDP such as travel and accommodation, according to the Treasury Board's "*Directive on the Management of Expenditures on travel, Hospitality and Conferences*".

## **4.0 ROLES AND RESPONSIBILITIES**

### **4.1 Members**

Members of the SAP-GSDP 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-GSDP. 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 SAP-GSDP and works closely with the Chair. In addition, the Secretariat:

- coordinates membership processes such as the affiliations and interests declarations and security clearances, and a membership list;
- coordinates the preparation of the meeting agenda, prepares background information packages for the SAP-GSDP and marks it according to the level to which it is protected under the "*Government Security Policy*," and drafts the record of proceedings for membership and the Chair's approval;
- maintains any information about the SAP-GSDP, 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-GSDP; and
- carries out additional duties as appropriate in support of the SAP-GSDP.

## **4.4 Executive Secretary**

The Executive Secretary is the Director General (TPD) who represents Health Canada and makes decisions about the SAP-GSDP and its advice. The Executive Secretary provides leadership and strategic advice in the management of the SAP-GSDP 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-GSDP 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.

## **5.0 MANAGEMENT AND ADMINISTRATION**

### **5.1 Transparency**

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

- ensuring that the meeting schedule is predictable, where possible; and
- posting SAP-GSDP materials, with confidential and personal information removed (when appropriate), on Health Canada's website including:
  - Terms of Reference;
  - Membership;
  - Summary of Expertise, Experience, and Affiliations and Interests;
  - Biographies of members;
  - Agenda; and
  - Records of Proceedings (RoP) and/or formal reports.

### **5.2 Meeting agendas**

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

### **5.3 Meeting notices and Invitations**

This teleconference 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 meetings**

The teleconference 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.

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.

### **5.5 Deliberations and Reports**

Deliberations during the teleconference 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-GSDP will be discussed.

Members provide advice to Health Canada in the form of recommendations. These recommendations are captured in a RoP. The SAP-GSDP 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-GSDP 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 those meeting documents will become part of the Central Registry file. In the event that the Chair and the Executive Secretary believe that the SAP-GSDP would benefit from broader stakeholder input, a portion of the meeting could become public.

## **6.0 REFERENCES**

The Health Products and Food Branch's "2007 *Guidance on Advisory Bodies*" and "*Policy on Public Input*" govern the Terms of Reference, and the management and administration of the SAP-GSDP. 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](http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/public-rev-exam/rev_reg_prod-exa-eng.php)