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SCIENTIFIC ADVISORY COMMITTEE ON MEDICAL DEVICES USED IN THE CARDIOVASCULAR SYSTEM

TERMS OF REFERENCE

The Scientific Advisory Committee (SAC) on Medical Devices Used in the Cardiovascular System (MDUCS) provides Health Canada with timely scientific, technical, medical and clinical advice related to the regulation of medical devices used in the cardiovascular system. Involvement of the scientific, medical and consumer communities in the regulatory review process enhances transparency and provides an opportunity for external advice, thus facilitating the device review process. The Committee provides Health Canada with advice and recommendations, but the decision-making responsibility remains with Health Canada.

These Terms of Reference of SAC-MDUCS were accepted on February 22, 2017.

1. MANDATE

To provide Health Canada with on-going and timely scientific, technical, medical and clinical advice on current and emerging issues related to the work of Health Canada pertaining to the evaluation of safety and effectiveness of devices used in the cardiovascular system.

Issues for committee consideration could include:

- specific issues related to the evidence in support of safety and effectiveness of a medical device provided in an application for a medical device license or an application for investigational testing authorization;
- emerging issues related to the technology, safety, effectiveness and clinical uses of devices used in the cardiovascular system;
- generic or device class post-market issues related to the use of medical devices used in the cardiovascular system; and
- Medical Devices Regulations, policy and guidelines.

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

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2. REPORTING STRUCTURE

The Committee reports to the Director General, Therapeutic Product Directorate (TPD). The Directorate is represented by the Director General (DG), or designate, who acts as the Executive Secretary to the Committee. Secretariat support is also provided by the TPD.

3. MEMBERSHIP

3.1 Selection of members

Members of the SAC-MDUCS are recruited through open and targeted nomination processes. Potential members are identified through consultation with a broad array of sources such as the Chair and members already on the SAC-MDUCS; Health Canada employees; health professional and scientific societies; academia; government and non-government agencies and/or the public. 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-MDUCS.

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 core members or nominees whereas other members are selected by the Executive Secretary in consultation with the Chair. The Executive Secretary, after consulting the Chair, may appoint, for a specific term, a Vice-Chair from among the members of the committee.

Membership of the SAC-MDUCS 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 may include lay representation. Members should include, but are not limited to areas such as:

- interventional radiology;
- cardiology;
- cardiovascular surgery;
- interventional cardiology;
- clinical perfusion;
- biomedical engineering;
- cardiac electrophysiology;
- neurovascular surgery.

3.2 Types of Members

The Committee has two types of members, core and *ad hoc* members, selected for their scientific/medical/technical expertise and knowledge. Core members are permanent members for the duration of their terms. *Ad hoc* members are invited by the Chair to serve for a specific topic or group of topics. The Committee may also have invited experts to address specific topics of discussion or members from the community to provide user perspective relevant to the work of the committee.

3.3 Tenure

Members are appointed by the Executive Secretary for a two-year term which may be extended for additional terms based on member's availability and willingness to continue their membership. 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-MDUCS has at least 10 core members and it should not exceed 15. 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 & Interests

As a condition of appointment, potential members of the SAC-MDUCS 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 web site 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 each 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, 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 and guest speakers serve on the SAC-MDUCS 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-MDUCS and serving as volunteers.

3.8 Travel and Expenses

Members and guest speakers are reimbursed for expenses incurred during their work on the SAC-MDUCS 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-MDUCS at any time upon 14 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-MDUCS 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.

4.0 ROLES AND RESPONSIBILITIES

4.1 Members

Members of the SAC-MDUCS 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 meetings (and public forums, if necessary);
- 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 each meeting when asked by the Executive Secretary or the Chair.

4.2 Presenters and Observers

Presenters and observers may not participate in discussions at the SAC-MDUCS meeting unless the Chair specifically invites them to do so. Only committee members may participate in the formulation of advice or recommendations to Health Canada.

4.3 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 a meeting, depending on the nature of the person's affiliations or interests;
- overseeing and chairing meetings, 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.

4.4 Vice-chair

At the request of the Chair, or in the case of the Chair's absence, the Vice-Chair will chair the meeting(s) and take on the Chair's other tasks, as required.

4.5 Secretariat

The Office of Science of the TPD acts as the Secretariat of the SAC-MDUCS. 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-MDUCS and works closely with the Chair. In addition, the Secretariat:

- coordinates membership processes such as the affiliations and interests declarations and security clearances, and maintains an up to date membership list;
- coordinates the preparation of meeting agendas, prepares background information packages for the SAC-MDUCS 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 SAC-MDUCS, its mandate, or work that may be posted on Health Canada's Web site;
- 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-MDUCS; and
- carries out additional duties as appropriate in support of the SAC-MDUCS.

4.6 Support to the Secretariat

Health Canada employees may assist the Secretariat with meeting logistics, document preparation, and other tasks.

4.7 Health Canada's subject-matter experts

Health Canada's medical, scientific, technical and program, policy, and other subject-matter experts support the work of a committee in a variety of ways, including:

- (a) preparing background documents such as research summaries and regulatory process overviews;
- (b) providing information about government policies and programs;
- (c) making a presentation or answering questions at a committee meeting;

4.8 Executive Secretary

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

4.9 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-MDUCS 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.

Documents leaving Health Canada, including electronic and work processing records, must be securely stored at all times and must be returned to Health Canada or permanently deleted upon request.

5.0 MANAGEMENT AND ADMINISTRATION

5.1 Transparency

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

- ensuring that meeting schedules are predictable, where possible; and
- posting SAC-MDUCS materials, on Health Canada's Web site including:
 - Terms of Reference
 - Membership
 - Summary of Expertise, Experience, and Affiliations and Interests
 - Biographies of members
 - Agendas
 - Records of Proceedings and/or formal reports and Health Canada's response.

5.2 Meeting agendas

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

5.3 Meeting notices and Invitations

All meetings are held at the call of the Executive Secretary in consultation with the Chair. Meeting attendance is by invitation only. Notices are 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

Meetings will be held up to three times per year in the National Capital Region. Rarely, additional meetings and/or teleconferences 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 ensure that no person who has not been approved by the Chair and Secretariat listen to the proceedings.

The SAC-MDUCS 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 meetings 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-MDUCS will be discussed.

At the discretion of the Executive Secretary and with the approval of the Chair, specific experts/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 that 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-MDUCS 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-MDUCS 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. As a condition of membership, members would agree to the audio recording of the meeting, to the RoP's publication on Health Canada's Web site and allow public access to slide presentations made during committee meetings. This agreement would be confirmed verbally at the start of every meeting. Invited guest speakers will be given the opportunity to review the draft RoP to ensure that their views are properly captured. The final RoP will summarize the proceedings to reflect the advice offered. The Secretariat is responsible for the distribution of the RoP.

When issues are of a general nature, the agenda and the record of proceedings will be posted on Health Canada's Web site 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-MDUCS would benefit from broader stakeholder input, a portion of the meeting could become public.

5.6 Review

The Secretariat will review the SAC-MDUCS, every 2 years, and will work with the Executive Secretary and the Chair to review the mandate, activities, Terms of Reference, and relevance of the SAC-MDUCS to ensure that it continues to meet ongoing needs of the Medical Devices Bureau. The TPD retains the prerogative to disband the body following such a review. Recommendations for improvement will be considered on an ongoing basis.

6.0 REFERENCES

The Health Products and Food Branch's "Health Canada Policy on External Advisory Bodies (2011)" (<http://www.hc-sc.gc.ca/ahc-asc/public-consult/res-centre/poli-eab-oc-eng.php>) and *Policy on Public Input* (<http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/public-rev-exam/index-eng.php>) governs the Terms of Reference, and the management and administration of the SAC-MDUCS.

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