EXPERT ADVISORY PANEL ON BREAST IMPLANTS

TERMS OF REFERENCE

The Expert Advisory Panel (EAP) on Breast Implants (BI) will provide Health Canada with timely advice related to the safety and effectiveness of silicone gel-filled breast implants. Involvement of scientific, medical and patient experts in support of regulatory decision-making is expected to enhance transparency in the decision-making process and provide an opportunity for broader external advice. The Panel will provide Health Canada with advice; the decision-making responsibility remains with Health Canada.

1. MANDATE

The Panel will provide advice on specific questions raised by Health Canada on the safety and effectiveness of the silicone gel-filled breast implants described in current device licence applications. The Panel will review documentation provided by Health Canada and listen to presentations by industry and other interested parties.

2. REPORTING STRUCTURE

The Panel reports to the Director General (DG) of the Therapeutic Products Directorate (TPD), who acts as the Executive Secretary to the Panel. The Therapeutic Products Directorate provides Secretariat support, responds to questions and provides information at the call of the Chair.

3. MEMBERSHIP

Individuals serving on an Expert Advisory Panel are chosen on the basis of their expertise and knowledge and they will not represent their firms, organizations or affiliations. They serve on the Panel as knowledgeable individuals in their own right and in the best interest of all Canadians.

The DG selects and appoints the members and Chair from a list of nominees identified by Health Canada through surveying health professionals, scientific societies, academia, and patient networks. Health Canada staff may not serve as members of the Panel.

The membership of the EAP-BI as a whole will cover areas of relevant expertise and knowledge such as chemistry, materials engineering, radiology, epidemiology, plastic/reconstructive surgery, psychology, ethics, rheumatology, toxicology, surgical oncology and patient needs and experience.

All Panel nominees are screened for preceived, potential or real conflicts of interest in accordance with *Health Canada's Conflict of Interest Policy*. Asummary of any identified conflicts of interest (based on information received through conflict of interest declaration forms), will be made available to the public.

4. PROPOSED TENURE / LIFE CYCLE

Panel members will review the documentation provided to them and will meet to hear presentations from the industry and the public; discuss (*in camera*) the questions posed by Health Canada; and provide advice. A two-day meeting will be held in Ottawa in the Fall of 2005. If necessary, additional *in camera* meetings of the panel by teleconference may be organized at the call of the Chair.

5. SECURITY CLEARANCE, CONDUCT AND CONFLICT OF INTEREST

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

All panel members must sign a confidentiality agreement supplied to them by Health Canada. Documents leaving the premises of the Therapeutic Products Directorate must be securely stored at all times and any confidential information provided must be returned or securely destroyed at the conclusion of the Public Forum process.

Panel members are expected to conduct themselves such that the use of their positions cannot be reasonably construed to be for their private gain, or that of any other persons or organization. All members shall protect and maintain, as confidential, all information received by them during the work of the Panel that is not public. Members must not discuss this confidential information with persons not on the Panel. They must not divulge information obtained from the *in camera* discussions of the Panel. Any discussion respecting the Panel work with the media or at conferences shall be done only by the Chair after authorization has been given by the Director General of the Therapeutic Products Directorate.

Guidance on conflict of interest is provided to potential members when discussing the appointment. Before appointment, all potential Panel members will be required to submit conflict of interest declarations to disclose to Health Canada any circumstance that may place, or be seen to place, the member in a real, apparent or potential conflict of interest. A summary of this information will be shared with the public. In situations where conflict of interest, or the appearance thereof, arises in the course of the work of a Panel member, the individual involved must declare its existence and the level of his/her participation in the discussion will be at the discretion of the Chair.

6. INDEMNIFICATION AND LEGAL ASSISTANCE

Members are eligible for indemnification and legal assistance under Treasury Board's "volunteer policy". Members are only protected when the advice given lies within the mandate of the Panel.

7. COMPENSATION

Members will be reimbursed for travel and accommodation expenses according to federal government policy.

8. MANAGEMENT AND ADMINISTRATION

The Panel will meet in Ottawa for a two-day meeting. The Panel will listen to, and may ask questions of industry representatives and members of the public who present material to the Panel. At the end of the Public Forum, there will be an *in camera* deliberation session for the Panel only. The agenda will be developed by the Secretariat of the Panel and approved by the DG, in conjunction with the Chair. Members will receive an agenda, briefing materials and other documentation as far in advance as possible prior to the meeting.

Discussion during the *in camera* portion of the meeting will be managed by the Chair and shall be open, frank and free-flowing. Panel members are expected to demonstrate fairness and a commitment to in-depth examination of the matter under review. Topics that do not fit within the mandate of the Panel are not to be discussed.

The advice of the Panel to Health Canada will be reached by consensus where possible. Lack of consensus may indicate uncertainty regarding the available information. In such cases, the Panel shall make a recommendation with respect to further study of the issue and/or a proposal for resolution. In cases where there is a real divergence of opinions that can not be resolved, the different opinions will be documented, and the number of members supporting each opinion recorded.

A record of proceedings (RoP) of the meeting will be circulated to members for review and final approval by the Chair. The RoP summarizes the proceedings and the advice regarding the specific questions. There will be no attribution for the recommendations reached during the *in camera* portion of the meeting. The RoP will be available to the public through the Health Canada Website.