Questions for the Expert Advisory Panel on Silicone Gel-filled Breast Implants

Preamble:

Health Canada is currently conducting a review of medical device licence applications for silicone gel-filled breast implants. At this time there are no silicone gel-filled breast implants licensed for sale in Canada.

The *Medical Devices Regulations* require manufacturers to ensure that their medical devices meet the safety and effectiveness requirements. The *Regulations* list eleven requirements to be considered, which when taken as a whole can be used to determine safety and effectiveness. Depending on the relative risk classification of a medical device, Health Canada conducts a premarket review of the manufacturer's submitted evidence of safety and effectiveness prior to making a decision with regard to licensing a medical device for sale in Canada.

As part of Health Canada's review process, a Scientific Advisory Panel (SAP) was convened earlier this year to consider several questions, regarding the evidence of safety and effectiveness presented by the manufacturers. This first meeting was held *in camera* to allow for a discussion of confidential commercial data.

In line with the Minister's commitment to transparency and openness, Health Canada will hold a public forum in the Fall 2005 to obtain additional input on the same questions discussed at the meeting in March 2005. As much of the manufacturer's information as possible will be provided to the public for review. However, the release of this information requires consent from the manufacturer, as it contains confidential commercial data provided to Health Canada in confidence. Health Canada's use of this information is governed by the *Access to Information Act*. The public will be invited to make presentations directly to an Expert Advisory Panel (EAP), or provide their input by mail, fax or online through a dedicated portal on the Health Canada web site.

The SAP and EAP members have been asked to consider the following questions concerning the safety and effectiveness evidence presented for the silicone gel-filled breast implants under review. Panel members will be provided with background information by the manufacturers, and will hear from members of the public prior to formulating their advice to Health Canada.

Health Canada will consider the advice received from the EAP, which includes many of the original members of the SAP, during its regulatory review of these medical device licence applications.

Context:

The context for the questions is found in Sections 10 to 20 of the *Medical Devices Regulations*, the Safety and Effectiveness Requirements. These sections provide information on how Health Canada evaluates the evidence of a medical device's safety and effectiveness, in particular:

Section 10. A medical device shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to:
a) Identify the risks inherent in the device;

b) If the risks can be eliminated, eliminate them;
c) If the risks cannot be eliminated:
    i) Reduce the risks to the extent possible,
    ii) Provide for protection appropriate to those risks, including the provision of alarms, and
    iii) Provide, with the device, information relative to the risks that remain; and
d) Minimize the hazard from potential failures during the projected useful life of the device.

Section 11. A medical device shall not, when used for the medical conditions, purposes or uses for which it is manufactured, sold, or represented, adversely affect the health or safety of a patient, user or other person, except to the extent that a possible adverse effect of the device constitutes an acceptable risk when weighed against the benefits to the patient and the risk is compatible with a high level of protection of health and safety.

Section 12. A medical device shall perform as intended by the manufacturer and shall be effective for the medical conditions, purposes and uses for which it is manufactured, sold or represented.

Section 13. During the projected useful life of a medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health or safety of a patient, user or other person is adversely affected.

The *Food and Drugs Act* and *Medical Devices Regulations* define a medical device label to include all materials distributed by a manufacturer with regard to a product. This includes educational material, instructions for use to the doctor and information provided to a user. In the case of breast implants Health Canada requires manufacturers to distribute patient information brochures with their devices. It is particularly important that these documents accurately reflect the known risks of a medical device and its potential benefits.

Further details with regard to Health Canada's expectations regarding the evidence of safety and effectiveness required for breast implants can be obtained from our guidance document "Preparation of a Premarket Review Document for Breast Implant and Tissue Expander Applications".

Questions:

The questions below are not specific to either a product or a manufacturer. The information presented to the Panel, and the Panel's advice may be product or manufacturer specific.

The questions posed are intended to facilitate the gathering of specific safety and effectiveness information. This process will allow Health Canada to consider all available information regarding the safety and effectiveness of these silicone gel-filled breast implants. Questions regarding the adequacy of the proposed patient labelling have also been proposed. It is important that women considering silicone gel-filled breast implants have access to appropriate information in order to make an informed decision.

1. Preclinical Data:
    a. Has the extent of gel bleed been adequately investigated and have questions regarding the potential health effects of any exposure to low molecular weight silicones been addressed?
    b. Have the potential mechanisms of rupture been adequately studied, to the extent that the lifetime of these devices *in vivo* can be sufficiently described in the patient labelling?

2. Clinical Data:
    a. Is the data provided sufficient to establish how the devices perform *in vivo*?
    b. Is the data adequately presented in the proposed product labelling?

3. Labelling
    a. Should additional information be provided to patients and physicians with regard to proactive implant follow-up procedures specific to the Canadian context?
    b. Have issues pertaining to recent literature regarding women who undergo augmentation procedures and a potential association with suicide been adequately addressed?
    c. Are the reported second generation effects, such as lower birth weights adequately documented, and should they be discussed in the labelling?
    d. Should additional information or physician training be provided to surgeons, regarding implantation best practices to help minimize complications?