December 15, 2011

Notice

Our file number: 11- 123108-504

Opportunity to be Heard in the Suspension of a Medical Device Licence

Purpose

The purpose of this notice is to provide guidance to medical device licensees on the process for an opportunity to be heard in respect of a medical device licence suspension according to sections 40 to 42 of the *Medical Devices Regulations* (the Regulations).

Introduction

One of the requirements of sections 40 to 42 is that a licensee be given an opportunity to be heard with respect to the proposed or ongoing licence suspension.

In the past, the Medical Devices Bureau (MDB) of the Therapeutic Products Directorate (TPD) has been responsible for recommending a device licence suspension and subsequently administering the opportunity to be heard process and providing a recommendation to the Director General on the reassessment of that licence suspension. In an effort to provide arms-length reassessments of licence suspensions, the responsibility for administration of the process and development of recommendations on these reassessments will now be transferred to TPD's Office of Science. This will more closely align the process for opportunity to be heard in licence suspension with the processes for reconsideration of decisions in the pre-market review of drugs and medical devices.

This notice communicates these operational changes to medical device licensees and informs them of the expectations associated with the opportunity to be heard process.

This notice will be effective immediately.

Process for an Opportunity to be Heard

Decision to Suspend

Before suspending a medical device licence for any of the reasons in s. 40(1) of the Regulations, MDB will review the licensee's history of compliance with the *Food and Drugs Act* and the Regulations. MDB will then assess the risk to the health and safety of patients and other users should the licence remain in force.

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In cases where the medical device is not considered to pose a health and safety risk, an opportunity to be heard will be granted prior to the suspension of the licence.

In cases where the medical device is considered to pose a health and safety risk to patients or other users, the licence will be immediately suspended after which the licensee will be provided with an opportunity to be heard.

Notification of a Suspension

When TPD determines that it has grounds to propose the suspension of a medical device licence under s. 40, the licensee will be notified in writing by the Director General with the reason for and the proposed date of the suspension. In this written notification the Director General will set out the steps and timeline for any corrective action should it be required. In situations when the device is found to pose a risk to health and safety, the licence will be immediately suspended according to s. 41 of the Regulations, and the licensee will be notified in writing of the reasons for the immediate suspension of the medical device licence. In either instance, the licensee will be reminded of his/her opportunity to be heard.

If a licensee chooses to pursue an opportunity to be heard, he/she should respond to the Director General in writing indicating his/her intent to pursue an opportunity to be heard within a reasonable period of time, normally within 10 days, after the receipt of notification. The Director General will acknowledge receipt of this request in writing.

Pursuing an Opportunity to be Heard in Writing

A licensee may pursue an opportunity to be heard by filing a comprehensive document with the Office of Science. The expectations for the content of this document will be identified by the Director General in his/her letter acknowledging the licensee's request for an opportunity to be heard. The comprehensive document should provide further clarification on information that was submitted to MDB to support the safety, effectiveness and quality of the licensed device.

It may also include information that was submitted during the licence application process or at the request of MDB. In this document the licensee should include its position and full supporting information as to why the suspension of the licence should be reconsidered. Any information that does not relate to the facts set out in the notification of suspension by the Director General will not be considered in the opportunity to be heard.

If a licensee chooses to pursue its opportunity to be heard under s. 40(3)(c) or s. 41(2) of the Regulations, TPD recommends that two copies of the comprehensive document be submitted within forty-five (45) calendar days of acknowledgement of receipt from the Director General. This time period helps ensure the completion of the opportunity to be heard process in an acceptable time frame and may be extended if requested by the licensee.

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Pursuing an Opportunity to be Heard in Writing with a Meeting or Teleconference

TPD will provide the licensee with further opportunity to discuss the medical device licence suspension and the comprehensive document during a meeting or teleconference. The licensee is encouraged to identify his/her desire for such a meeting upon initiation of the opportunity to be heard process. This meeting can be completed in person or by teleconference and should be held within a reasonable period of time following submission of the comprehensive document. In most cases this should be no less than fourteen (14) days after filing of the comprehensive document.

Meeting attendees would include the medical device licensee, TPD Director General (or his/her delegate), and representatives from the Office of Science and MDB. MDB will also present on the basis for the medical device licence suspension. The meeting will neither be used to debate issues nor will a decision be made during the meeting. The meeting will serve solely as a forum for discussion.

Decision

The Office of Science will review both the material presented in the comprehensive document and at the meeting, and provide a recommendation to the Director General.

The Director General will inform the licensee of the outcome of the review within twenty-one (21) calendar days from the date of the meeting or teleconference, or thirty-five (35) calendar days from the receipt of the comprehensive document if the opportunity to be heard is conducted in writing only.

Contact Information

To request a meeting for an opportunity to be heard, please contact:

Director General's Office
Therapeutic Products Directorate
Health Canada
1600 Scott Street, Holland Cross
Tower 'B', Address Locator3106B
Ottawa, Ontario
K1A 0K9

Telephone: 613-957-6466
Fax: 613-952-7756
E-mail: TPD-General-DPT-General@hc-sc.gc.ca

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To file a comprehensive document, please contact:

Office of Science
Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
Health Canada
1600 Scott Street, Holland Cross
Tower ‘B’, Address Locator3102C3
Ottawa, Ontario
K1A 0K9

Telephone: 613-948-4623
Fax: 613-941-1812
E-mail: Policy_Bureau_Enquiries@hc-sc.gc.ca

For questions regarding the content of this notice, please contact:

Bureau of Policy, Science and International Programs
Therapeutic Products Directorate
Health Canada
1600 Scott Street, Holland Cross
Tower 'B', Address Locator 3102C5
Ottawa, Ontario
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