

June 1, 2005

NOTICE

Our file number: 05-111977-811

Re: *Guidance for Industry - Private Label Medical Devices*

Health Canada is pleased to announce the release of the final *Guidance for Industry, Private Label Medical Devices*. This guidance clarifies how private label manufacturers may meet their medical device licensing regulatory responsibilities.

A draft version of this document was released for stakeholder consultation in December 2004 with the comment period ending on January 31, 2005. Comments were received from seven stakeholders and all but one expressed support for the initiative. This final version of the guidance has been updated to include additional clarification in response to comments that were received. A separate Questions and Answers (Q&A) Document has been created to respond to additional comments and questions received during the consultation process. The guidance and Q&A document are attached and also are available on the Therapeutic Products Directorate (TPD) website.

Medical Devices Bureau has developed revised application forms for new and amended private label licences and an accompanying guidance document for completing these forms. These documents are also available on the TPD website.

The implementation date of the *Guidance for Industry, Private Label Medical Devices* is June 1, 2005 with a 6-month transition period. By December 1, 2005 it is expected that private label manufacturers will have applied to Health Canada for medical device licences for all of their private label medical devices.

Should you have any questions or comments regarding the content of the guidance, please contact

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GUIDANCE FOR INDUSTRY

Private Label Medical Devices

Published by authority of the
Minister of Health

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Health Products and Food Branch

<p>Our mission is to help the people of Canada maintain and improve their health.</p> <p style="text-align: right;"><i>Health Canada</i></p>	<p>HPFB's Mandate is to take an integrated approach to the management of the risks and benefits to health related to health products and food by:</p> <ul style="list-style-type: none"> • Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. <p style="text-align: right;"><i>Health Products and Food Branch</i></p>
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Également disponible en français sous le titre: Instruments médicaux de marque privée

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidances.

1. PURPOSE

The purpose of this document is to provide guidance on regulatory requirements for private label manufacturers of Class II, III and IV medical devices.

2. SCOPE

This guidance applies to new and amended licence applications for private label medical devices submitted by private label manufacturers.

3. BACKGROUND

Health Canada recognizes that certain businesses, typically those that retail products to the general public, sell medical devices under their own name or trademark while having limited or no control over the activities covered in the definition of a manufacturer (see Section 4.1 below). These manufacturers are commonly referred to as private label manufacturers. Although private label manufacturers may not undertake any of the activities outlined in the definition, they do fall within the definition of “manufacturer” since they sell medical devices under their own name and the tasks listed in the definition are being performed “**on their behalf**”; i.e., on behalf of the private label manufacturer. Therefore, private label manufacturers and the devices that they market must comply with the requirements of the *Medical Devices Regulations*.

4. POLICY STATEMENT

Private label manufacturers must comply with the requirements of the *Medical Devices Regulations*. In order for private label manufacturers to fulfil their medical device application requirements, Health Canada will accept a letter of authorization, written by the original manufacturer, to grant permission to Health Canada to cross-reference the safety and effectiveness information and quality systems certificate that the original manufacturer has attested to or included in their medical device licence application to Health Canada in accordance with the *Medical Devices Regulations*.

4.1 Definitions

The term “manufacturer” is defined in the *Medical Devices Regulations* as follows:
"manufacturer" means a person who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf. (*fabricant*)

"original manufacturer" has the same meaning as “manufacturer” in the Regulations.

"private label manufacturer" means a person who sells a private label medical device under their own name or trademark.

"private label medical device" means a medical device that is identical in every respect to a medical device manufactured by an original manufacturer and licensed by Health Canada, except that the device is labelled with the private label manufacturer's name, address and product name and identifier.

4.2 Private Label Manufacturer's Regulatory Responsibilities

- Private label manufacturers must apply for and obtain a medical device licence in order to sell their Class II, III or IV private label medical devices in Canada
- A cross-referenced private label device licence application must include a letter signed by a senior official of the original manufacturer on the original manufacturer's letterhead in which the senior official:
 - attests that the device is a "private label medical device";
 - provides permission to the private label manufacturer and to Health Canada to cross-reference the original medical device licence application and the supporting safety, effectiveness and quality systems information held by the original manufacturer or by Health Canada; and
 - agrees that the original manufacturer would provide, upon request from Health Canada, any information respecting the safety, effectiveness and quality of the private label medical device.
- When an original manufacturer's medical device licence is amended, the private label medical device licence is automatically amended. However, a private label manufacturer is required to amend their device licence if they are making a change in the device name, a change in the manufacturer's name or if an identifier of the device is being changed, added or deleted.
- All other provisions of the *Food and Drugs Act* and *Medical Devices Regulations* and the *Fees in Respect of Medical Devices Regulations* apply to a private label medical device and private label manufacturer and are the responsibility of the private label manufacturer. These provisions include having systems in place to handle complaints and to manage mandatory problem reporting and recalls. The private label manufacturer must notify Health Canada of any recalls of their licensed private label medical devices.
- Private label manufacturers that do not hold ISO 13485/13488 quality systems certificates under the Canadian Medical Devices Conformity Assessment System (CMDCAS) are subject to inspection by the Health Products and Food Branch Inspectorate.