

## Private Label Medical Devices

### Questions and Answers

- Q1. When a medical device is recalled, do both the original manufacturer and the private label manufacturer have to notify Health Canada?
- A. Yes, both must notify Health Canada.
- Q2. Will there be specific application forms for private label medical device licences?
- A. Yes, application forms for private label medical devices and a guidance for completing these application forms are available on the Therapeutic Products Directorate website.
- Q3. Can a private label manufacturer apply for a licence at the same time as the original manufacturer?
- A. No, the private label manufacturer may submit an application for a new medical device licence for a private label medical device only **after** a medical device licence has been issued to the original manufacturer.
- Q4. When does a private label manufacturer submit an application to amend their private label medical device licence for the addition of new identifiers (for example [e.g.], catalogue numbers)?
- A. An amendment application may be submitted by the private label manufacturer only **after** the corresponding identifiers (e.g., catalogue numbers) for the original manufacturer's medical device have been licensed by Health Canada.
- Q5. Does a private label manufacturer have to obtain ISO 13485/88 certification in order to apply for a private label device licence?
- A. No, the private label manufacturer does not have to submit ISO 13485/88 certification in order to apply for a private label device licence. The private label manufacturer may cross-reference the quality systems information submitted by the original manufacturer in the original manufacturer's device licence application.
- Q6. Can a private label manufacturer cross-reference the original manufacturer's information if the original manufacturer does not have a Canadian licence for that medical device?
- A. No, the original manufacturer must have a Canadian licence for that device. Otherwise, Health Canada would not have access to the original manufacturer's information.
- Q7. Why would a private label manufacturer have to apply for a device licence amendment every time the original manufacturer amends a licence? An amendment by an original manufacturer should automatically cross-reference the private label device licence in a database.
- A. The guidance document has been revised to respond to this comment. The requirement for the private label manufacturer to apply for a corresponding amendment has been removed. The private label manufacturer's licence will automatically be amended at the same time that the original manufacturer's licence is 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.

- Q8. Can a private label manufacturer include the original manufacturer's name and contact information on the labelling of a private label medical device?
- A. The labelling must include the information set out in subsection 21(1) of the *Medical Devices Regulations*. The name and address of the private label manufacturer must be provided as per paragraph 21(1)(b). The original manufacturer's name and contact information could also be included as long as they were presented in a manner that would not contravene the clarity requirements of subsection 21(2).
- Q9. Are private label manufacturers who have their own safety, efficacy information and quality systems certificate required to cross reference the information in the original manufacturer's application?
- A. No, a private label manufacturer would apply for a medical device licence by submitting or attesting to their own safety and efficacy information and quality system certificate.
- Q10. Why are private label manufacturers subject to inspection?
- A. The scope of inspections in Canada is described in the Health Products and Food Branch Inspectorate document, "Inspection Strategy for Medical Device Companies", which was implemented in the first quarter of 2004. Under this strategy, medical device companies that do not have ISO 13485/13488 certification are subject to proactive inspection. A company holding an ISO 13485/13488 certificate may also be inspected if there is an indication of noncompliance or suspected noncompliance. The strategy document includes links to related policy and regulatory guidance documents and is available on the Inspectorate website.
- Q11. Will a private label medical device continue to be classified as such when non-material changes have been made that do not affect the functioning of the item, such as a change in colour, addition of trademarks, or other slight modifications. For example, a thermometer that has a different colour or to which a branding identification has been added or one that has a handle that has been slightly modified.
- A. The device must be identical to the device that is licensed by the original manufacturer. The addition of a branding identification would be considered to be within the definition of a private label medical device. However, any variations in colour or design must be included in the original manufacturer's licence.
- Q12. When will the private label medical device licence guidance/policy become operational.
- A. Final posting on the Health Canada web site is targeted for June 1, 2005. There will be a six month transition period. Private label manufacturers are expected to have their applications for a private label medical device submitted to Health Canada by December 1, 2005.

Q13. Are there any fees associated with private label medical device licence applications?

A. Private label medical devices are currently exempt from Division 2 - Fees for the Examination of Medical Devices Licence Applications contained in Part 3 - Medical Devices Fees of the *Fees in Respect of Drugs and Medical Devices Regulations*. Therefore, there are no fees associated with the examination of private label medical device applications or private label licence amendment applications. Health Canada will review the costs associated with service delivery every three years and will propose new or amended fees to reflect the results of that review.