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Update: Notice to Stakeholders - Health Canada's Regulatory Approach to Commercial Reprocessing of Medical Devices Originally Labelled for Single Use

May 4, 2016

Our file number: 16-105050-455

Single-use medical devices are those labelled by their manufacturers to be used only once. For years, hospitals have reprocessed (that is [i.e.] cleaned, sterilised and disinfected) some of these devices for reuse to save costs. More recently, hospitals have begun contracting companies to perform this service. Through discussions on the new patient safety legislation (Bill C-17), Health Canada has concluded that it has authority under the existing *Food and Drugs Act* and *Medical Devices Regulations* (the Regulations) to require that these commercially reprocessed devices meet appropriate standards for safety, effectiveness and labelling. With regard to reprocessing on-site by hospitals, however, Health Canada will continue to respect the current oversight provided at the provincial and territorial level.

Under the federal regulatory framework, companies that reprocess and distribute medical devices originally authorized and labelled for single use to Canadian healthcare facilities will be held to the same requirements as manufacturers of new devices. This means they must meet requirements for licensing, quality system management, labelling, investigating and handling complaints, maintaining distribution records, conducting recalls, reporting incidents and informing Health Canada of any changes to the information in their licence application.

Health Canada is continuing to work with the commercial reprocessing industry to bring their activities and products into compliance with the Regulations. The department has met with industry associations as well as reprocessing companies to promote awareness of the regulatory requirements and determine their readiness to meet them. Companies are expected to apply for device and establishment licences as appropriate, and prepare to phase out the supply of non-compliant devices. Reprocessed devices that have obtained licences must meet the terms of their market authorizations, including labelling. Certain reprocessing companies have actively engaged Health Canada in an effort to bring their activities and reprocessed devices into compliance. These reprocessing companies have begun to submit applications and receive licences for reprocessed single use devices; however, it is not anticipated that all reprocessed single use medical devices will be licensed by September 1, 2016, the end of the initial transition period. As such, Health Canada is extending its initial transition period by an additional 12 months. By September 1, 2017, all commercially reprocessed devices are expected to be in compliance with the Regulations, whether they are reprocessed domestically or outside Canada. If you have not already taken steps to work with Health Canada, you are strongly encouraged to do so as soon as possible. Non-compliant devices and activities will continue to be subject to risk-based compliance enforcement.

Additional Information

For questions about medical device licensing requirements, please contact the Medical Devices Bureau at device_licensing@hc-sc.gc.ca

Mandatory medical device problem reports from industry should be emailed to mdpr@hc-sc.gc.ca or faxed to 613-954-0941.

The Canada Vigilance Program provides tools for health care professionals and consumers to report device-related incidents. For more information on the Program, please contact CanadaVigilance@hc-sc.gc.ca.

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