IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

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Re-Use of Single Use Devices

In February 2015, Health Canada announced its regulatory approach to commercial reprocessing of medical devices originally labelled for Single Use.

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.

Re-Use of Single Use Devices

These companies must meet the following requirements:

- Licensing
- Quality Management System (QMS)
- Conducting Recalls
- Mandatory reporting of incidents
- Inform Health Canada of any changes to the information in their licence application

Transition Period

- By September 1, 2016 all commercially reprocessed single use devices are expected to be in compliance with the Regulations.
- Health Canada will meet with industry associations in the next few months to promote awareness of the regulatory requirements.
- Health Canada has currently licensed one reprocessed single use device (compression sleeve).

Decorative Contact (Non-Corrective) Lenses

- Comment Period on proposed regulatory amendments to regulate decorative contact lenses as a Class II medical device closed January 3, 2015).
- Comments are being considered and anticipate to proceed to final publication in 2015.