IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

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Decorative Contact (Non-Corrective) Lenses

- Amendment to the *Medical Devices Regulations* for Non-Corrective Contact Lenses (NCCL) and Labelling of Class II medical devices was published in Canada Gazette II on July 29, 2015.

Decorative Contact (Non-Corrective) Lenses

- These regulatory changes introduce two changes to the Medical Devices Regulations in respect of licence application requirements for Class II medical devices including one to give effect to the *Bill C-313 An Act to Amend the Food and Drugs Act* which received Royal Assent on December 14, 2012

Decorative Contact (Non-Corrective) Lenses

- As part of the work to classify non-corrective contact lenses (NCCLs) as devices under the *Food and Drugs Act* and to license them under the *Medical Devices Regulations*, the first amendment exempts manufacturers of NCCLs from the regulatory requirement to establish therapeutic effectiveness as these products have no therapeutic effect.
- These amendments come into force on July 16, 2016.

Decorative Contact (Non-Corrective) Lenses

- The second amendment requires manufacturers of all Class II medical devices (including non-corrective contact lenses) to begin submitting copies of their product labels as part of their licence application.
- This amendment comes into force on July 16, 2015.

Regulatory Transparency and Openness Initiatives

- Posting of Regulatory Decision Summaries
  - Positive decisions for new Class IV medical device licence applications filed after April 1, 2015
  - Negative decisions for new Class IV medical device licence applications filed after April 1, 2016

Final Guidance Documents

- Guidance on the Risk-based Classification System for Non-In Vitro Diagnostic Devices (non-IVDDs) published on June 12, 2015.
- Notice on electronic labelling of certain medical devices sold or imported into Canada published on June 26, 2015
- Guidance on Labelling of Medical Devices, Not Including *In Vitro* Diagnostic Devices published on July 29, 2015