IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

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Overview

- Changes to:
  - Policy
  - Regulatory Transparency and Openness
  - Guidance

Policy

- Intent to Reclassify Disinfectants and Sterilants for Use on Medical Devices as Medical Devices
  - Notice published on Health Canada web site on September 14, 2016
  - Intent for reclassification is to be in line with international regulators
  - Work is ongoing to develop an action plan indicating the transition process, timelines and licensing requirements

Policy

- Preparation of Medical Device Regulatory Activities in an electronic-only format
  - Notice published on Health Canada web site December 14, 2016
  - Sets out regulatory activity types that can be submitted in an electronic format
  - Paper copies of regulatory activities set out in the notice will no longer be accepted after April 1, 2017.

HPFB 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
- Posting of annual inspection summary reports
- Posting of regulatory Forward Plans
- Posting of safety review summaries
- Expansion of the Health Product Register
- Making performance data publically available

Regulatory Transparency and Openness Initiative

- Posting of Regulatory Decision Summaries

  Regulatory Decision Summaries (RDSs) explain Health Canada's decisions for certain health products seeking market authorization.

  They include:

  - Purpose of submission
  - Reason for the decision
  - Summaries of certain submissions that were accepted into review and subsequently cancelled by the sponsor

- 110 (as of Feb 10) positive decisions for new Class IV medical device licence applications posted after April 1, 2015
- No (as of Aug 24) negative decisions for new Class IV medical device licence applications posted after April 1, 2016

Regulatory Transparency and Openness Initiative

- Posting of List of New Safety Signals under Review and Summary of the Safety Reviews (SSR) completed
  - As part of the ongoing commitment to openness and transparency initiative, Health Canada (HC) is publishing summaries of its safety reviews
  - Each summary outlines what was assessed, findings, and the action taken by HC (if any)
- Three SSRs posted in 2016

Guidance Documents

- Preparation of Regulatory Activities in the “Non-e-CTD Electronic-Only Format
- Applications for Investigational Testing Authorization (ITA) for Medical Devices, in the Non-eCTD Electronic-Only Format
- Final Guidance on the Preparation of Premarket Medical Device and Licence Amendment Applications for Dermal Fillers

Upcoming Documents

- Revisions to Guidance document on regulation of medical devices manufactured from or incorporating viable or non-viable animal tissue or their derivatives
- Revisions to the Preparation of an Application for Investigational testing- Medical Devices

Questions/comments

- Thank you for your attention!