Regulatory and Policy Updates
Therapeutic Products Directorate
Health Canada

Kimby N. Barton
Interim Director
Medical Devices Bureau
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 publicly 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!