Regulatory and Policy Updates
Therapeutic Products Directorate
Health Canada

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Policy

• Medical Device Single Audit (MDSAP) Transition Plan published December 4, 2015
  – January 1, 2017- January 1, 2019: During the implementation phase, Health Canada will accept certificates issued under both Canadian Medical Devices Conformity Assessment System (CMDCAS) and MDSAP
  – January 1, 2019: Health Canada will only accept MDSAP certificates
Regulatory Transparency and Openness Initiative

Transparency Measures Introduced by Vanessa’s Law

- Requires Health Canada to publicly disclose decisions on therapeutic product authorizations and details of any orders for a recall, test/study, label change or reassessment

- Subject to regulations, requires sponsors to publicly disclose clinical trial information, such as registration and disclosure of results

- 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
Regulatory Transparency and Openness Initiative

• Posting of Regulatory Decision Summaries

  • 41 (as of Jan 21) positive decisions for new Class IV medical device licence applications posted after April 1, 2015

  • Negative decisions for new Class IV medical device licence applications to be posted after April 1, 2016
Guidance Documents

• Guidance for the Labelling of In Vitro Diagnostic Devices (IVDDs)

• Guidance for Health Care Professionals on Special Access and Custom-Made Medical Devices

• Guidance for the Risk-based Classification for In Vitro Diagnostic Devices (IVDDs)