Regulatory and Policy Updates
Therapeutic Products Directorate
Health Canada

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Overview

• Medical Device Single Audit Program (MDSAP)
• Regulatory Review of Drugs and Devices
• Scientific Advisory Panel on Software as a Medical Device (SaMD)
• Cannabis
• Guidances
Medical Device Single Audit Program (MDSAP)

• In 2015, Health Canada announced the intention to implement MDSAP as the mechanism to demonstrate compliance with the quality management system requirements as of January 1, 2019.

• Manufacturer feedback and concerns:
  – Auditing Organization’s capacity and readiness,
  – Increased audit duration and costs for smaller manufacturers
  – Health Canada’s timeline to transition
Medical Device Single Audit Program (MDSAP)

- Health Canada has developed communications to ease transition which includes webinars with stakeholders and website landing page.
- Further analysis on audit duration for smaller manufacturers is ongoing.
Regulatory Review of Drugs and Devices

• Transformation into modern, agile regulatory system that supports better access to therapeutic products based on healthcare system needs
  – More timely access to drugs and devices
  – Enhanced use of Real World Evidence (RWE)
Digital Health Division

• Newly-created division will review
  – Software
  – Diagnostic, therapeutic, and cosmetic radiation devices
  – Cybersecurity
  – Artificial intelligence
  – Mobile apps

• Will also be involved in outreach and guidance development activities
Pre-Submission Scientific Advice

• Develop tools and processes that will improve pre-submission meetings:
  – Influence the design of clinical trials for devices
  – Generate appropriate data to meet regulator needs
  – Improve communication between HC and medical device industry

• e-learning tools in development

• Pre-clinical meeting pilot to be launched in Fall 2018
SAP-SaMD

• HC convened a Scientific Advisory Panel on Software as a Medical Device on January 26, 2018, to provide expert advice

• Panel members included regulator, physicians, software developers, patient group, and provided feedback on draft guidance document

• Guidance will be posted for external consultation
Cannabis

• Cannabis legalization in Canada targeted for July 2018

• New regulations being developed to address recreational and therapeutic use of cannabis

• Medical devices intended for use with cannabis (e.g., delivery devices, drug-device combination products) will be subject to additional requirements under these new regulations
Upcoming Documents

• Guidance on Software as a Medical Device (SaMD)

• Final Notice on the Reclassification of High-Level Disinfectants and Sterilants Intended for Medical Devices and associated guidance documents
Questions/comments

Thank you!