IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

Therapeutic Products Directorate
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Overview

- Medical Device Single Audit Program (MDSAP)
- Scientific Advisory Committee on Digital Health Technologies (SAC-DHT)
- Guidances
- Medical Devices Action Plan

Transition to Medical Device Single Audit Program (MDSAP)

December 2015 - Health Canada announced that the CMDCAS program would be replaced by MDSAP as of January 1st, 2019.

Health Canada worked in collaboration with international regulatory MDSAP partners to develop mitigation measures to address stakeholders' feedback (audit cycle & audit duration/costs)

MDSAP
January 1, 2019

MDSAP – mandatory

Health Canada will continue to monitor the transition closely to ensure an effective and successful transition to MDSAP

Mitigation measures

1. Reduction of audit duration for SMEs (meeting the criteria)
2. Allowing manufacturers to transition to MDSAP while carrying-on with their existing certification cycle under CMDCAS

Status of Transition to Medical Device Single Audit Program (MDSAP)

MDSAP Survey

December 2017 - about half of companies planning to transition expected to do so in the second half of 2018

3000* facilities registered with MDSAP

Approximately 3000* MDSAP certificates or transition packages received by Health Canada to date as of February 8, 2019

•Representing just over 90% of our manufacturers.

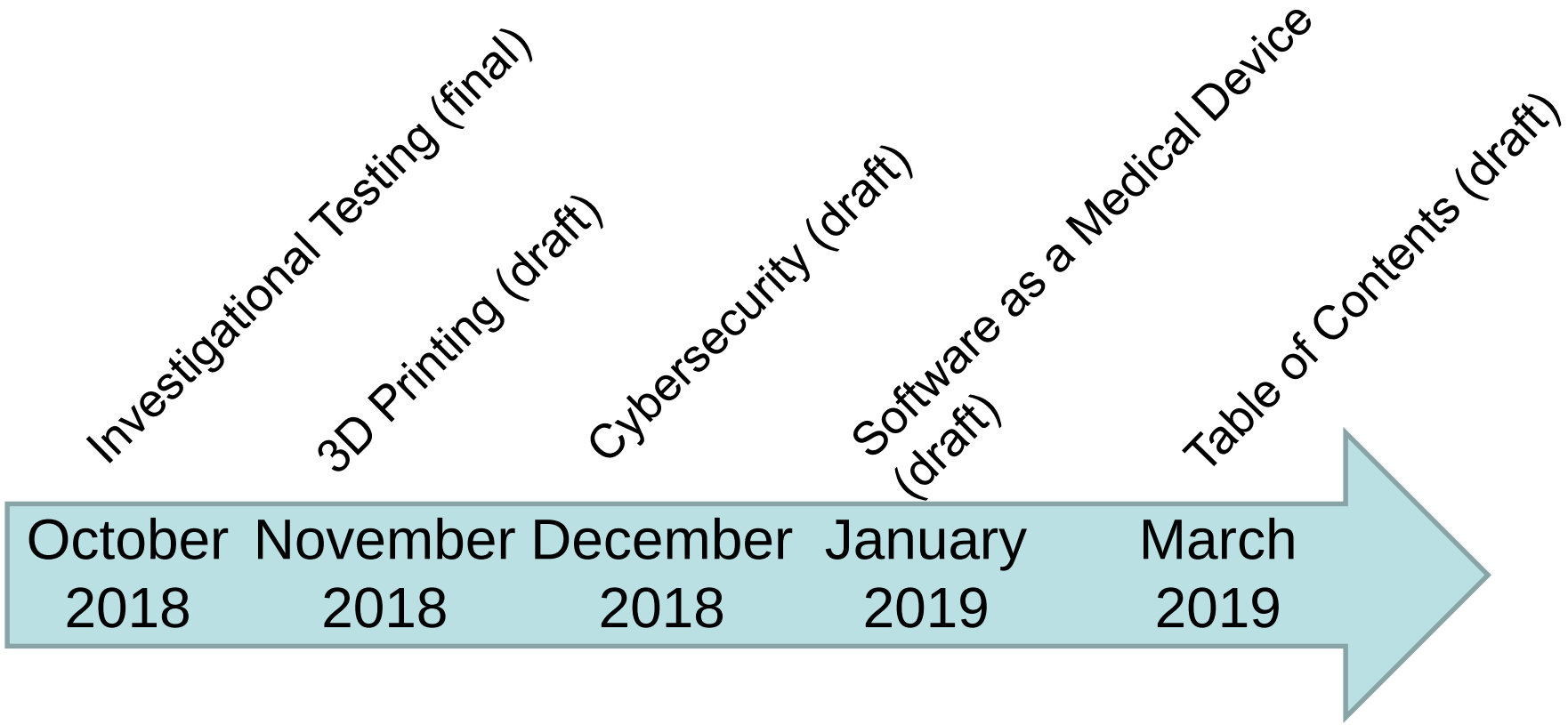
Continue to monitor

MDSAP will bring:
•greater alignment of rules with regulators in other jurisdictions
•important benefits to manufacturers operating in multiple markets

SAC-DHT

- First meeting held on November 23, 2018, on cybersecurity
- Participation from academia, security research community, healthcare, government, and patient groups
- Record of Proceedings to be posted on Health Canada website
- Next meeting on May 9, 2019, on Artificial Intelligence

New Guidance Documents



Medical Devices Action Plan

- 3 pillars designed to strengthen regulatory framework

Improving how devices get on the market

Strengthening monitoring and follow-up

Providing more information to Canadians

- Positive feedback from stakeholder information sessions held in December and January

Medical Devices Action Plan

Improving how devices get on the market

- Allow healthcare professionals to file applications for investigational testing, in addition to manufacturers, introduce GCP conformance
- Draft guidance document on clinical evidence requirements (November 2019)
- Scientific Advisory Committee on Health Products for Women (Spring 2019)
- MDSAP

Medical Devices Action Plan

Strengthening monitoring and follow-up

- Publish draft regulations to compel manufacturers for more information (June 2019)
- Draft guidance on use of RWE to support regulatory decisions (June 2019)
- Expand the scope of the Canadian Medical Devices Sentinel Network to include additional healthcare settings such as long term care facilities and private clinics (June 2019)
- Hire additional inspectors (March 2019)

Medical Devices Action Plan

Providing more information to Canadians

- Launch searchable public web portals on clinical information and incidents
- Publish and update data extract of incidents, complaints, and recalls (January 2019)
- Increase the scope of Regulatory Decision Summaries (January 2019)
- Publish and update inspection reports with clearer language (December 2019)

Questions/comments

Thank you!