IMDRF International Medical Device Regulators Forum

Regulatory and Policy Updates

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Overview

- Medical Devices Action Plan Update
- Medical Device Single Audit Program (MDSAP)
- Scientific Advisory Committees (SACs)
- Guidances
- Regulatory Review
- Disinfectants

Medical Devices Action Plan Update

- Increased collaboration with international partners to share safety information
- Allergan breast implants product withdrawal
- Targeted stakeholder consultation on Investigational Testing (April 29 – June 21,2019)
- Published draft regulations on June 15, 2019, establishing ability to compel post-market information

Medical Devices Action Plan Update

- Searchable extract of medical device incident data published and updated on website
- Clinical evidence guidance
- Regulatory Decision Summaries
  - Amendment applications
  - New Class III, IV applications
- Published regulations for reporting of incidents by hospitals in June 26, 2019, and coming into force December 16, 2019

Transition to Medical Device Single Audit Program (MDSAP)

- As of August 2019, 99.0% of medical device licences are supported by MDSAP

- HC has suspended licences of most non-compliant manufacturers

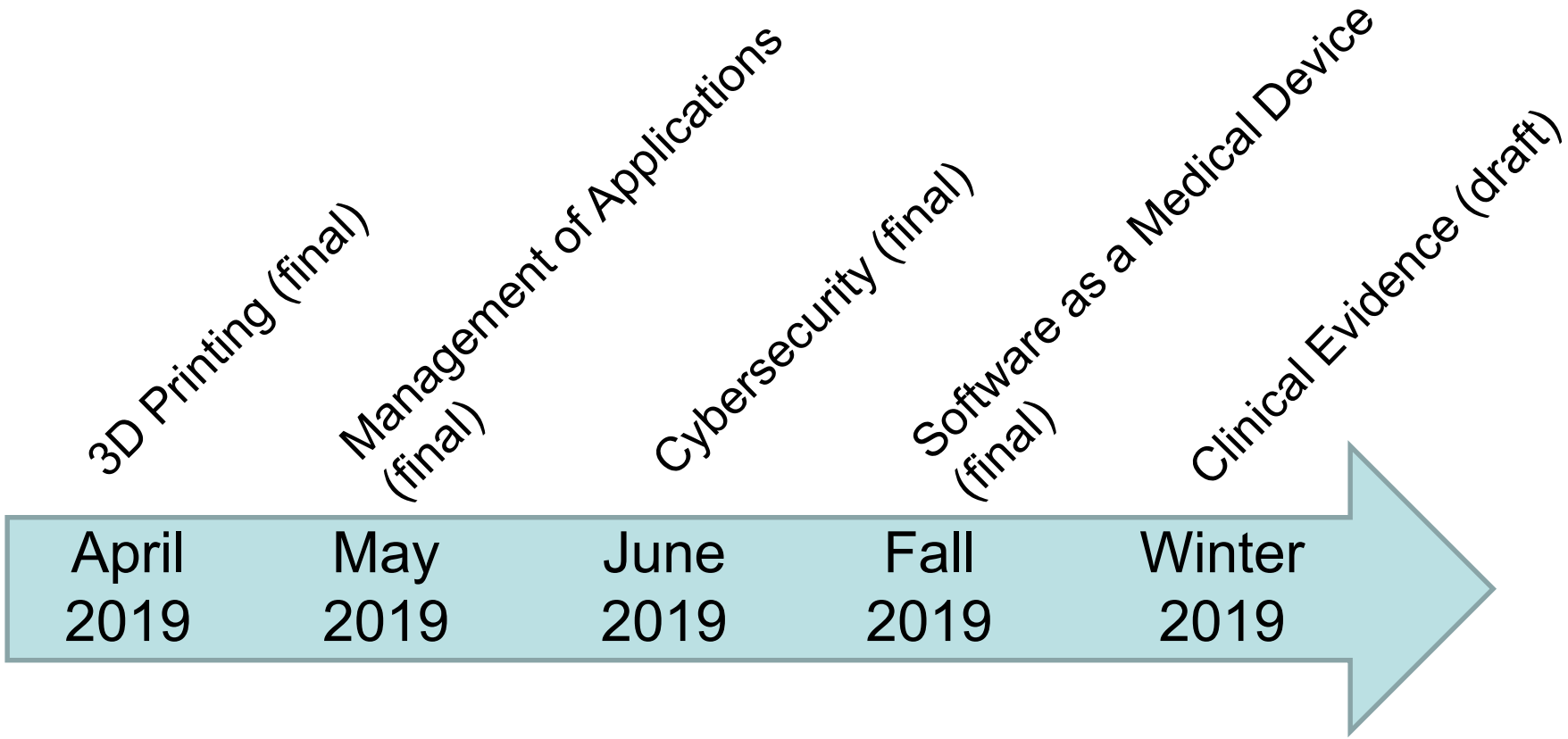
SAC-Health Products for Women (HPW)

- First meeting held May 16-17, 2019
- Participation from academia, patient group, women's health expert, health care professionals
- Discussed clinical evidence requirements, lifecycle management, and knowledge transfer to patients and healthcare professionals
  - Vaginal meshes and breast implants used as case studies

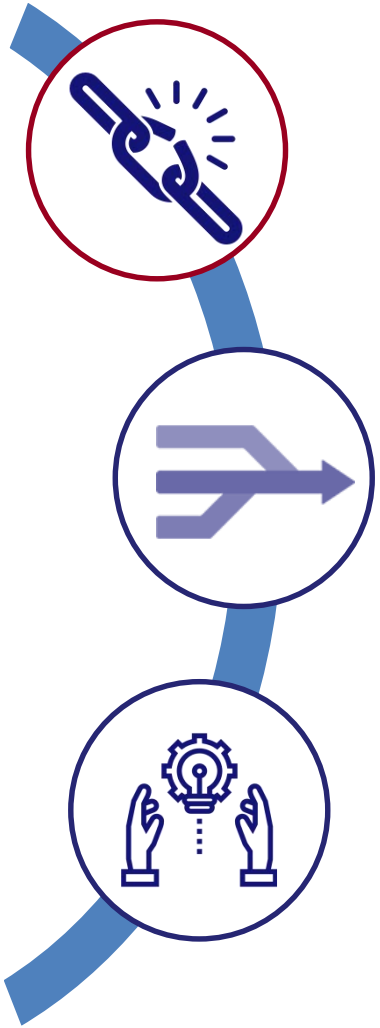
SAC-Digital Health Technologies (DHT)

- Second meeting held May 9, 2019, on artificial intelligence (AI)
- Participants included healthcare professionals, software developers, academia, lawyer, patient group
- Committee provided recommendations related to AI regulation on topics such as algorithm verification and validation, post-market surveillance, ethics, and interoperability

New Guidance Documents



Regulatory Review of Drugs and Medical Devices



1. Modernize the Existing Framework – Drugs

Remove old regulations that are redundant or create unnecessary barriers to innovation

2. Create Agile Regulations – Drugs and Devices

Create a simplified, streamlined framework, that strengthens oversight and provides flexibility to enable product innovation

3. Enable Advanced Therapeutic Products – Drugs and Devices

Enable and better regulate advanced therapeutic products by considering new approaches

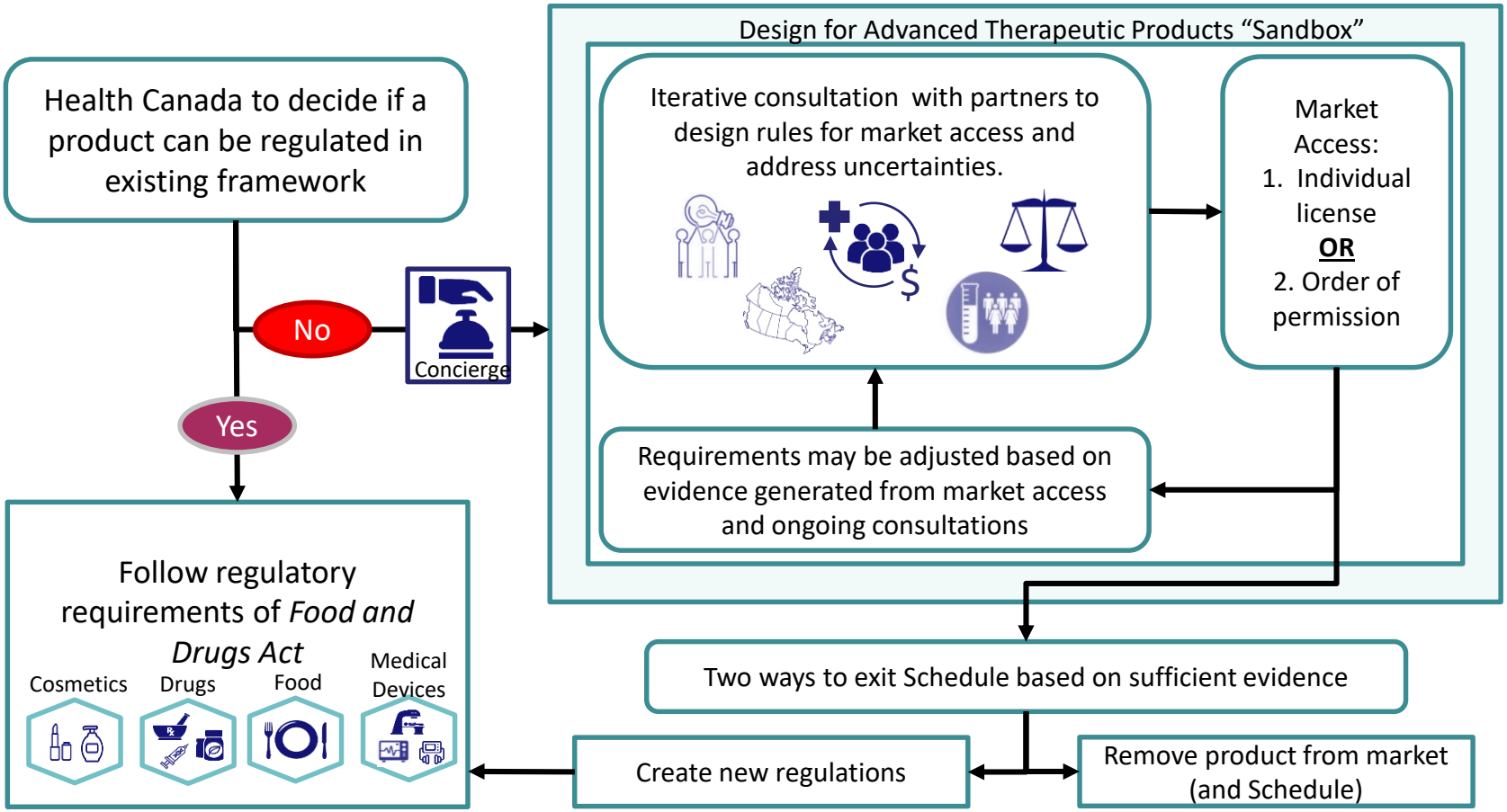
Regulatory Review

- Areas of focus for medical devices:
  - Clinical Trials (Investigational Testing)
  - Advanced Therapeutics

Clinical Trials

- Proposed Changes
  - Allow Health Canada to develop regulations that are flexible and provide risk-based oversight for the conduct of clinical trials on a range of products with various risk profiles
  - Allow the Minister to impose terms and conditions on clinical trial authorizations
  - Require certain information about a trial be made publicly available as outlined in regulations

Advanced Therapeutics



Disinfectants

- Transition period extended for 18 months to March 1, 2021, to allow manufacturers to comply with device framework

- Website notices will be updated

Questions/comments

Thank you!