Regulatory and Policy Updates
Therapeutic Products Directorate
Health Canada

David Boudreau
Executive Director
Medical Devices Bureau
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
- 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

- 3D Printing (final) - April 2019
- Management of Applications (final) - May 2019
- Cybersecurity (final) - June 2019
- Software as a Medical Device (final) - Fall 2019
- Clinical Evidence (draft) - Winter 2019
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

Health Canada to decide if a product can be regulated in existing framework

No

Concierge

Yes

Follow regulatory requirements of Food and Drugs Act

Cosmetics  Drugs  Food  Medical Devices

Design for Advanced Therapeutic Products “Sandbox”

Iterative consultation with partners to design rules for market access and address uncertainties.

Market Access:
1. Individual license
2. Order of permission

Requirements may be adjusted based on evidence generated from market access and ongoing consultations

Two ways to exit Schedule based on sufficient evidence

Create new regulations

Remove product from market (and Schedule)
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!