



# Health Canada Update

2019 MDSAP Forum  
Washington, DC



# MDSAP Transition

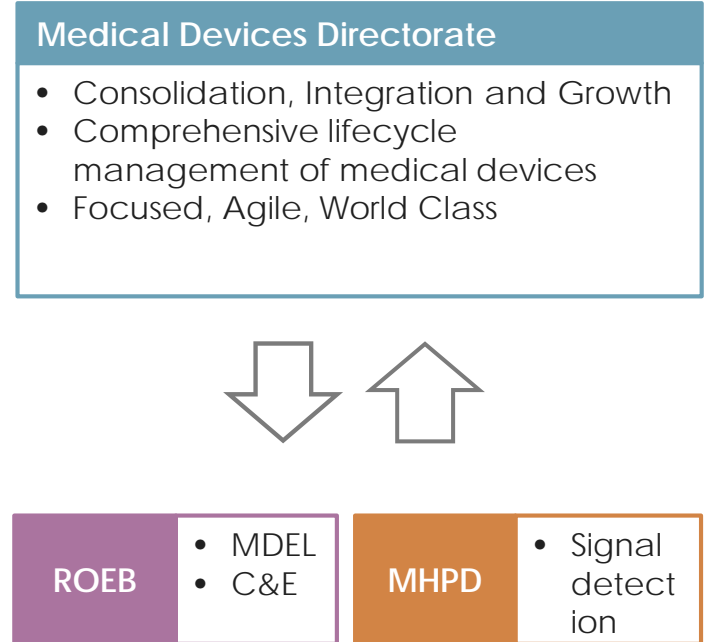
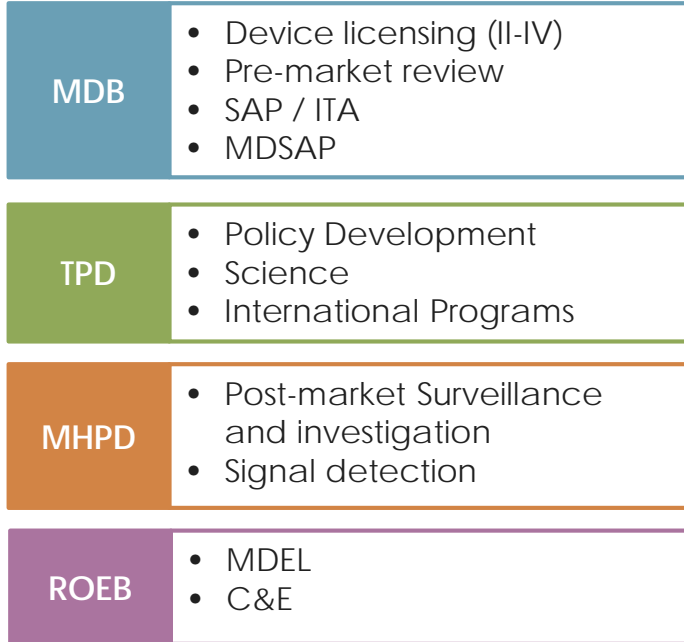
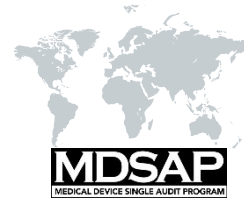


## Essentially Complete!

Since the November 1<sup>st</sup> renewal, **99.6%** of licensed devices are covered under the transition plan

...but there is still work left to do!

# New Medical Devices Directorate



# New Post-Market Regulations



## Foreign Risk

Enhanced requirements for reporting foreign events and risks

## Annual Summary

Annual summary Report of post-market S&E

## Issue Analysis

New ability to request analysis of specific post-market S&E issues

# New Post-Market Regulations

CG I publication and  
consultation

2019

June  
2020

CG II publication

Coming into force

Dec.  
2020

May 2020 update: due to the Covid-19 pandemic, the publication and coming into force of the new post market regulations have been delayed. A new timeline has not yet been announced.



**MDSAP**  
MEDICAL DEVICE SINGLE AUDIT PROGRAM