Health Canada Update

2019 MDSAP Forum
Washington, DC
MDSAP Transition

Essentially Complete!

Since the November 1st renewal, 99.6% of licensed devices are covered under the transition plan

...but there is still work left to do!
New Medical Devices Directorate

| MDB   | • Device licensing (II-IV)  
|       | • Pre-market review  
|       | • SAP / ITA  
|       | • MDSAP  

| TPD   | • Policy Development  
|       | • Science  
|       | • International Programs  

| MHPD  | • Post-market Surveillance and investigation  
|       | • Signal detection  

| ROEB  | • MDEL  
|       | • C&E  

Medical Devices Directorate

• Consolidation, Integration and Growth  
• Comprehensive lifecycle management of medical devices  
• Focused, Agile, World Class  

ROEB • MDEL  
• C&E  

MHPD • Signal detection
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

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.