Health Canada Santé Canada

Canada

Update – Medical Devices Bureau

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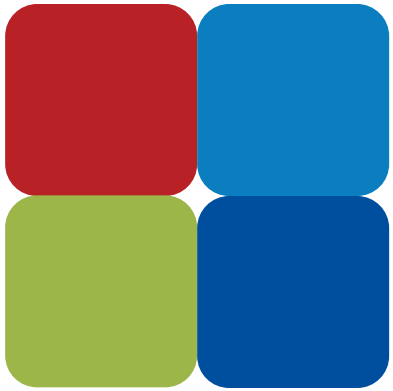
YOUR HEALTH AND SAFETY... OUR PRIORITY.

Outline



Regulatory Review of Drugs and Devices

Overview of MDB's initiatives

MDSAP

Overview & update on the transition

Performance Improvement

Improving tools & process
Leading to enhanced client experience

Cost Recovery Renewal Initiative

Revised fee proposal for drugs and medical devices

Regulatory Review of Drugs and Devices (R2D2)

MDB is leading two initiatives under R2D2

Device advice	To improve communication of regulatory requirements and expectations to stakeholders: • Interactive e-Learning course • Development of a formal meeting framework
Digital Health	March 28, 2018 – establishment of the Digital Health Division • Review of software, diagnostic, therapeutic, and cosmetic radiation devices • Will undertake newer digital health related initiatives: cybersecurity, artificial intelligence, 3D printing, mobile apps, software as a medical device, etc.

Outcomes

New e-learning courses	Formal device advice framework	Targeted pre-market review of digital health technologies	Improved access to innovative digital health devices

Transition to MDSAP – on track

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

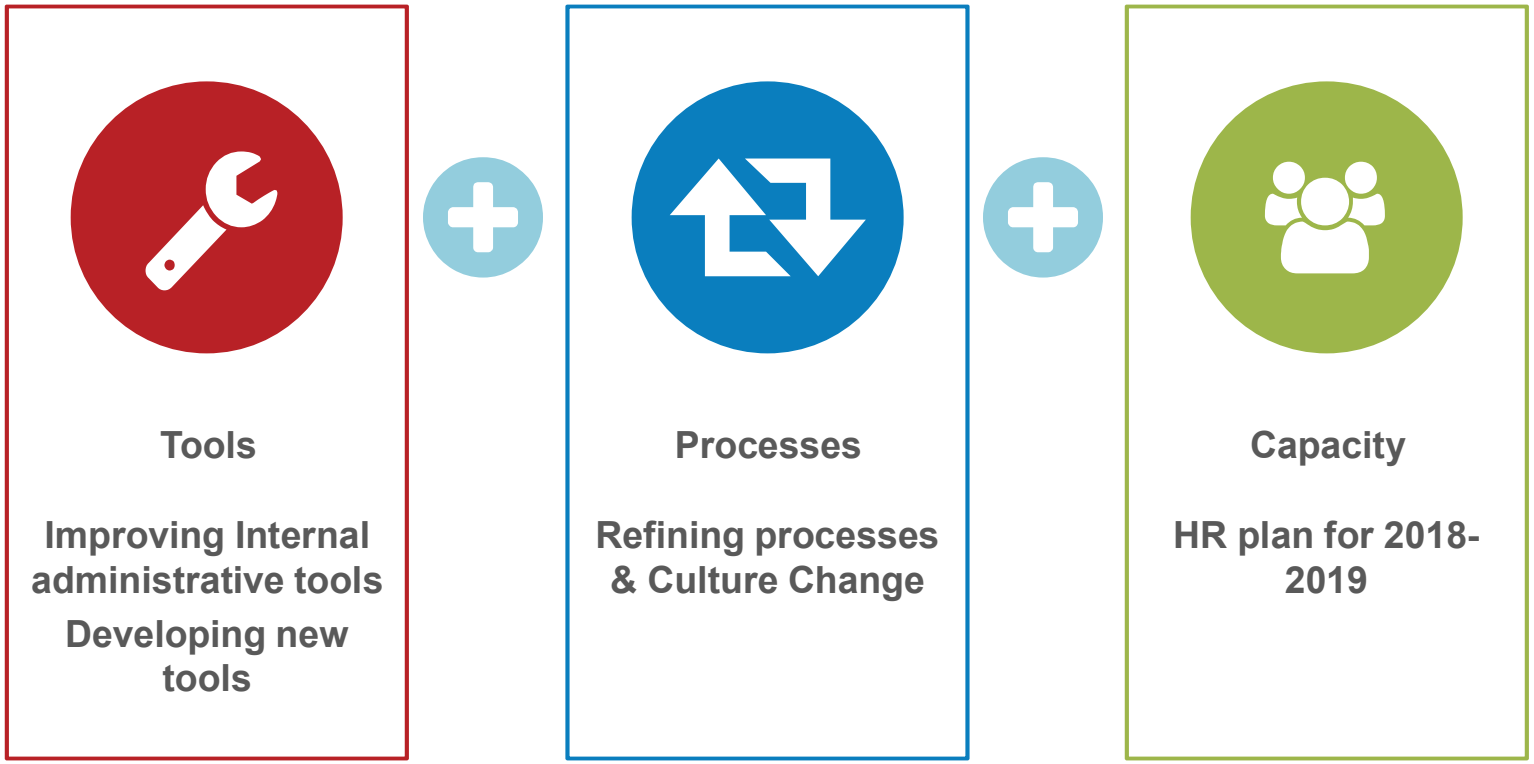
1. Reduction of audit duration for SMEs (meeting the criteria)
2. Allowing manufacturers to transition to MDSAP while carrying-on with their existing certification cycle under CMDCAS

MDB - Performance Improvement Plan

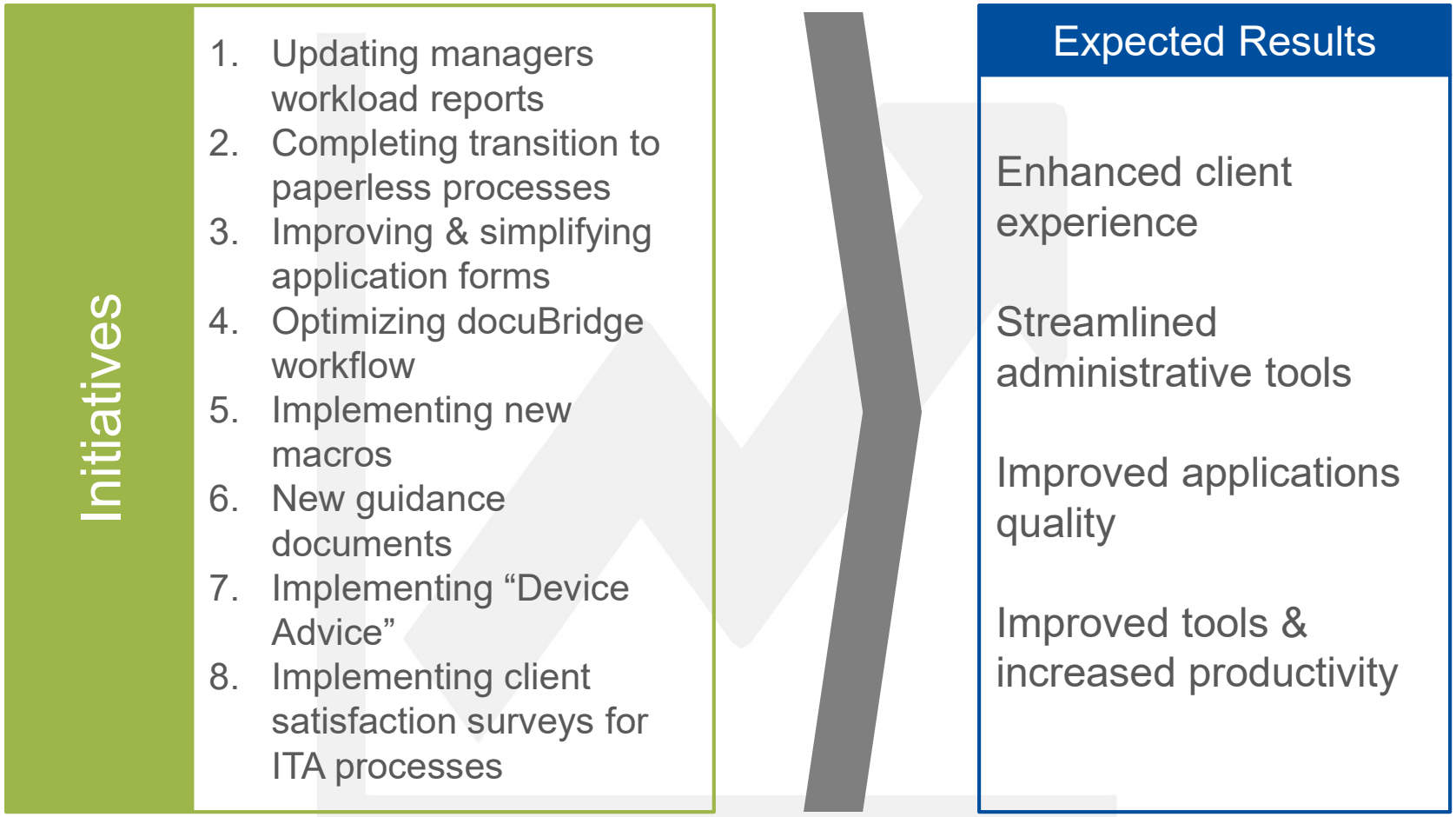
Type	Target Days	On time YTD (current quarter)	Goals (FY18-19)			
			Q1	Q2	Q3	Q4
Class II New	15	79 %	85%	90%	95%	100 %
Class III	60	76%	65%	75%	90 %	
Class IV	75	79%	70%	75%		
Class II Amendments	15	72%	50%	65%		
Private Labels	15	74%	55%	70%		
ITA	30	80%	75%	80%		

MDB – Performance Improvement Plan

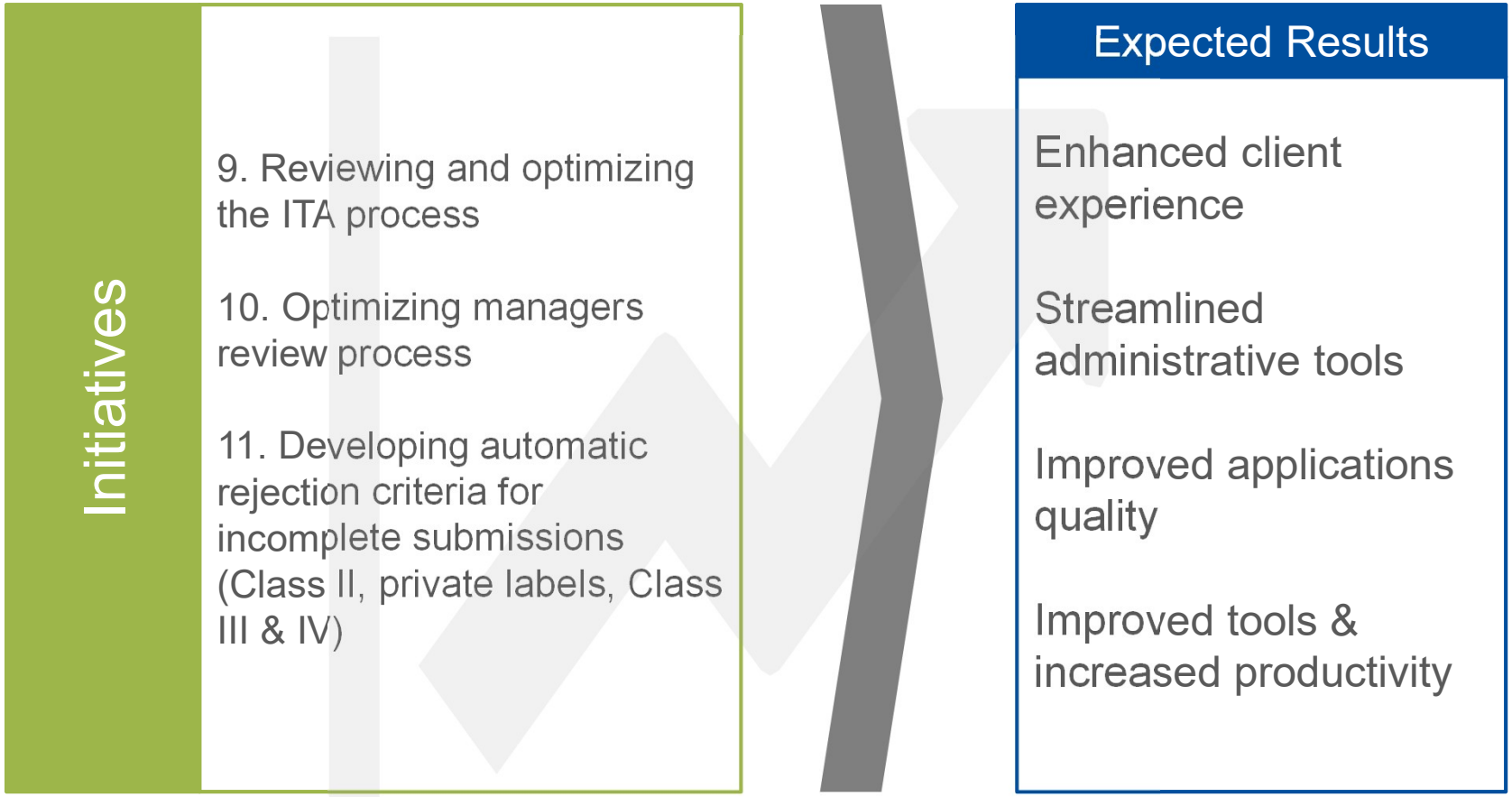
Meet review application target by Q1 2019 - 100%
Improving & Optimizing



MDB – Performance Improvement Plan



MDB – Performance Improvement Plan



Cost Recovery Renewal Initiative

April 2011
First update to fees since mid-90s

October 2017
Consultation on the fee proposal

June 2018
Revised Fee Proposal for Drugs & Medical Devices

- Revised fee setting ratio to 75% for Pre-market fees for drugs and medical devices (50% for veterinary drugs), and to 67% for all Right to Sell fees
- Four-year phase-in period (max 25% increase for pre-market & Establishment , max 50% right to sell)
- Expanded fee relief for small business including waivers to all Pre-market fees (50%) and Right to Sell and Establishment Licence fees (25%); and
- Expanded mitigation to waive fees for all publically funded health care institutions

Implementation Spring 2019

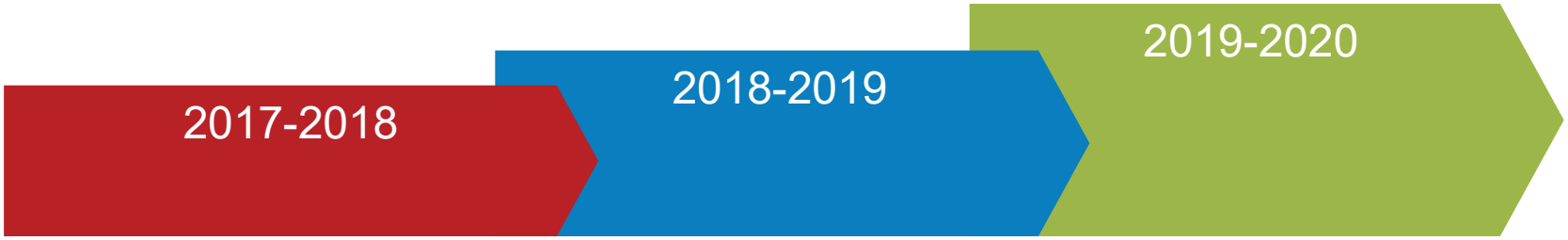
Guiding Principles

Be reasonable and fair - Minimize impact on small business - Apply appropriate mitigation measures and fee waivers - Make fee increases gradual and predictable - Ensure accountability

Organizational Changes

Increasing capacity is key

To enhance client experience & ensure effective and timely processing of application



2017-2018

Initiate expansion & culture change

- Digital Health Division – 9 new positions
- Investigational Testing – 2 new positions

2018-2019

Position MDB to meet increasingly evolving stakeholders needs and fast pace of innovation

- Internal reorganization
- Continue to increase capacity – 16 new positions

2019-2020

Plans to develop new capacity in MDB

New !

- Policy & international
- Stakeholder engagement
- Internal quality

Questions?

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https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices.html

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/international/transition-medical-device-single-audit-program.html