Orthopaedic Surgical Manufacturers Association

Educational Program

Thursday, July 19th, 2018

Renaissance Montreal Downtown Hotel

Montreal, Canada

OSMA Continental Breakfast

7:15am – 8:15am

President

- Welcome
- Meeting Logistics
  - Sign-In Sheet
  - Name Tags
  - Group Dinner

6:00 pm Zibo Restaurant
Centre-ville
1235, Robert-Bourassa
Montreal, QC H3B 0C3

- Introductions
- Reading of Meeting Guidelines

Reading of Meeting Guidelines

While attending OSMA meetings, the members are not to discuss or exchange information on markets, prices, commercialization methods, and/or costs of products or services. These same restrictions apply both to meeting topics and to any social activity connected to the OSMA meeting.

During any discussion of standards, guidelines or specifications for testing, no commercial aspects shall be discussed. The discussion must be confined to technical, engineering, safety and regulatory factors. No agreement for adherence to any standard, guidelines or testing parameters for specific products or services shall be made.

Brexit Update

Phil Brown
Director
Technical & Regulatory
ABHI

Phil Brown

Phil started his career at Smith and Nephew qualifying as a Graduate of the Royal Society of Chemistry in 1984, before joining the Company's Woundcare Regulatory Affairs team at the time when the Medical Device Directive was being enacted. Company moves to Genzyme Biosurgery, Quintiles, Wright Medical Technology and more latterly Kinetic Concepts Inc., (an Acelity company), included work with novel technologies, liaising with National Authorities, the European Commission, Trade Associations and standards bodies on issues related to regulation and ethics.

Phil extended his Trade Association work by joining the ABHI in June 2016 as the Director responsible for Technical and Regulatory matters. Phil is a Fellow of TOPRA and lectures at the Sheffield Hallam University on medical device Regulatory frameworks.

ABHI

Association of British HealthTech Industries

Brexit – MedTech Implications

July 2018

Medical Technologies

History and Industry Asks…

HOTEU; April 2017; Summary

ABHI's recommendations represent a clear view for UK MedTech, focused on five themes;

1. Ensuring regulatory stability and leveraging the global reputation of UK regulators
2. Maintaining favourable terms for trading within and outside the EU, along with an integrated domestic policy to support investment, competitiveness and export performance
3. Support for manufacturing, including continuing to address the domestic skills gap and ensuring that the UK can attract the best talent globally
4. Bespoke support for our vibrant SME community
5. Enhanced collaboration with the health and care system.

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Medical Technologies

History and Industry Asks…

HOTEU; April 2017; Regulatory Recommendations

- Ensuring regulatory stability and leveraging the global reputation of UK
- A pragmatic UK approach to compliance with the current and future European regulation for medical devices
- The UK remaining part of the CE marking regime for MedTech. This requires mutual recognition of the CE-mark between the UK and EU and, where practicable, similar arrangements with other jurisdictions
- UK Notified Bodies (NBs) remain within the existing European network and oversight mechanisms. They should continue to be designated to assess devices for the EU and UK market.
- Authorised Representatives of manufacturers based outside the EU should still be allowed to be domiciled in the UK.
- MHRA retains influence over, and oversight of, the EU regulatory system, through formal engagement with the European Commission's new stakeholder body, the Medical Devices Co-ordination Group (MDCG), and has full access to Eudamed.
- MHRA increases influence over global regulatory harmonisation, through UK membership of the international medical device regulators forum (IMDRF).

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History and Industry Asks…

HOTEU; April 2017; Regulatory Recommendations

- Continued application of International Standards for Quality Management Systems (ISO 13485) and Risk Management (ISO 14971)
- An assessment of the training places available to support MedTech companies and a focus on the training of Regulatory Affairs professionals.

ABHI

Medical Technologies

History and Industry Asks…

HOTEU; April 2017; Trade Recommendations

- Ensure free trade with Europe on the most beneficial terms possible
- Protect other Free Trade Agreement benefits with non-EU countries
- No increased customs duties against imports into the UK
- Ensure UK Customs laws facilitate trade without onerous barriers to duty reliefs or fair customs treatments
- Align regulation to facilitate trade
- Minimise any increased administrative costs and border delays
- Allow transition measures to provide for a reasonable time frame for change implementation without resulting cost increases
- Facilitate less regionalisation/duplication of funding and human resource for exporters
- Increased grant funding for SMEs to support export activity
- Introduce a UK Export Tax Credit Scheme.

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Medical Technologies

History and Industry Asks…

HOTEU (update); January 2018; Regulatory Recommendations

- The UK remaining part of the CE marking regime for MedTech. This requires mutual recognition of the CE-mark between the UK and EU and, where practicable, similar arrangements with other jurisdictions
- UK Notified Bodies (NBs) remain within the existing European network and oversight mechanisms. They should continue to be designated to assess devices for the EU and UK markets
- Authorised representatives of manufacturers based outside the EU should still be allowed to be domiciled in the UK
- MHRA to remain formally engaged with the European Commission's new stakeholder body, the Medical Devices Co-ordination Group (MDCG), and has full access to the Eudamed database, so retaining insight and influence over the EU regulatory system.

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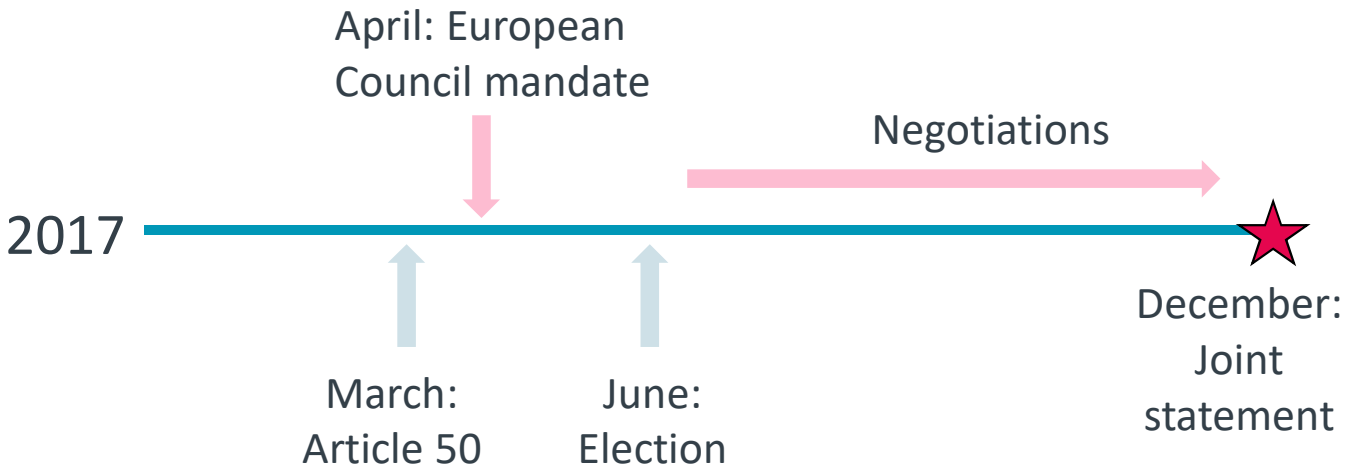
Timing is Crucial…

THE STORY SO FAR…



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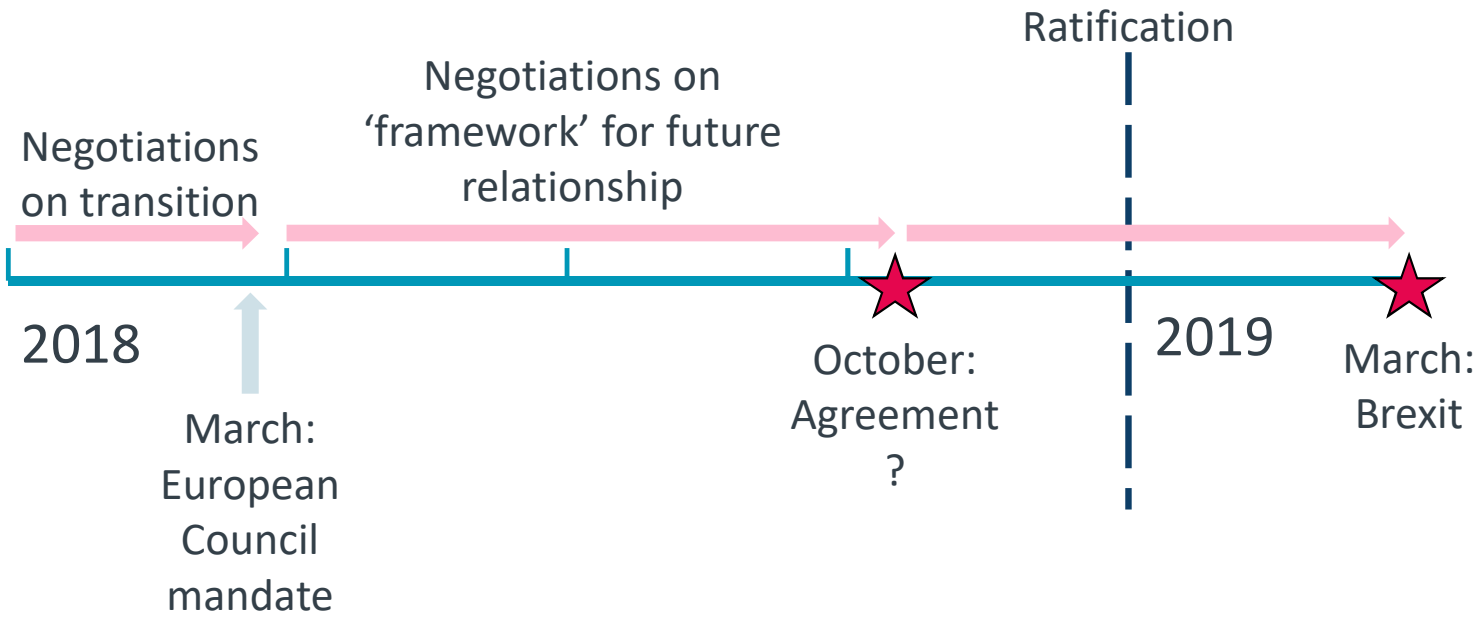
THE STORY SO FAR…



THE STORY SO FAR…

Negotiations and after March 2019?

- UK officially becomes ‘a third country’
- MDR only partially implemented
- Future relationship negotiations begin in earnest
- Transition period – until Dec 2021
  - MDR fully implemented
  - IVDR still undergoing transition
  - Legal standing of MDR
- Role of UK during implementation period

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CHALLENGES

Working with Whitehall : Implementing Multiple Scenarios

NO DEAL	
What is needed?	By when?
Immigration system for all EU citizens	March 2019
Customs system for all EU imports and exports	
New regulators for current EU functions	
Agreements with third countries	

NEGOTIATED OUTCOME	
What is needed?	By when?
New immigration system – depending on deal	End of transition
New customs system – depending on deal	
New regulators – depending on deal	
Agreements with third countries	

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SO WHAT?

ABHI Key Considerations

- Regulatory alignment
- Movement of goods

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SO WHAT?

Regulatory Alignment: Concerns

- Will the EU Withdrawal Bill be enacted essentially in current form?
- Will there be mutual recognition with the EU?
- Will the Transition Agreement be agreed, or will the UK “crash out of the EU” (Hard Brexit?)
- Will the UK Government introduce laws bringing MDR/ IVDR into UK law?
- ……or will there be something different?

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SO WHAT?

Regulatory Alignment: Concerns

UK Law from 30 March 2019

EU law enacted as UK law (Directives):
Become "stand-alone" UK law:
MDD/ AIMD/ IVDMDD

EU law with direct effect (Regulations):
Become part of "stand-alone" UK law ONLY if both in force AND "applicable" at **29 March 2019**:

Most provisions of MDR and IVDR will not be part of UK Law on 30 March 2019

Transition

EU law will apply in UK until 31 December 2020

EU LAW

Gradual applicability of MDR and IVDR:

26 May 2020: MDR fully applicable

26 May 2022: IVDR fully applicable

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SO WHAT?

Regulatory Alignment: Will UK Government enact MDR and IVDR

For

1. "Close, warm relationship" = Mutual Recognition
2. MHRA instrumental in drafting
3. MDR/ IVDR represent the latest thinking on best practice
4. Access to other markets that recognise the CE mark

Against

1. Need to follow ECJ decisions?
2. c.60 sets of secondary legislation (UK no input to these)
3. Desire to be seen to have "sovereignty"

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Regulatory Base, post-March 2019

"[Highlighting] … the leading role played by the UK in the recent negotiations of new EU regulations for medical devices and in-vitro diagnostic medical devices. The UK has already welcomed the new requirements of these regulations to protect patients while encouraging innovation."

Lord O'Shaughnessy,

Parliamentary Under-Secretary of State, Health (September 2017)

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Medical Technologies

Regulatory Base, post-March 2019

"Elements of the new regulations have been applied directly in UK law since May [2017], meaning devices can now be legally placed on the UK market if they are in conformity with the new regulations, invoking all relevant requirements.

As it stands, the EU (Withdrawal) Bill would maintain this position beyond March 2019."

Lord O'Shaughnessy,

Parliamentary Under-Secretary of State, Health (September 2017)

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Specific MDR Questions…

- Implementing and Delegated Acts
- European Court of Justice
- EUDAMED
- Notified Bodies
- Authorised Representatives
- Person Responsible for Regulatory Compliance
- Distribution Chains
- Post-Market Surveillance
- Allied Regulations

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Implementing and Delegated Acts;

Convergence vs. Divergence

- MDR identified for regulatory stability and certainty
- Implementing and Delegated Acts
  - Regulatory Convergence or Divergence
  - How to deal with these ‘post-Brexit’
  - MDD+
  - Acts or guidelines?
- Input beyond March 2019 and the role of the MHRA

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European Court of Justice;

A hurdle too far?

- European Court held as ‘backstop’ to MDR issues, particularly those related to vigilance.
- What to include as part of transposition?
- Change of ‘backstop’?

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EUDAMED;

Public Health Risk?

- ‘Go Live’ date for several modules due just before May 2020
- Cliff-Edge scenario would mean EUDAMED not implemented
- Vigilance module;
  - Major contributors are UK and Germany
  - Public Health issue if reporting diluted?
- UK alternative?
- ‘Pay-as-you-go’ scenario?

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Notified Bodies;

Red Herring?

- Notified Bodies under considerable strain re. capacity and timings
- UK Notified Bodies working on Plan ‘B’
- Need for Notified Body to be EU domiciled
- Change in Notified Body number to be expected;
  - MDR
  - MDD
- Ensure dialogue, NOW!

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Authorised Representatives;

Plan for your EU Representative…

- MDR requires AR to be EU domiciled – will a Mutual Recognition Agreement allow for AR to be in the UK?
- Potentially requires;
  - New labelling
  - New contracts
  - Person Responsible for Regulatory Compliance
  - New PMS requirements
- Will UK require an 'Authorised Representative' to manage UK transposition of MDR?

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Person Responsible for Regulatory Compliance (PRRC);

- Authorised Representatives require the services of a PRRC;
- Duplication of roles
- Another question of ‘Mutual Recognition’
- Who will hold any Technical Files?

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Distribution Chains;

Product supply issues – Customs and Tariffs…

- Many ‘touch-points’ across Europe for manufacture and distribution of finished as well as in-process goods
- Customs points potentially as a ‘bottle neck’
- Ireland / Northern Ireland border
- Procedure Packs / Virtual Manufacturing
- New Technologies
- Prohibitive additional costs?

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Post-Market Surveillance;

Another red herring?

- PMS processes should not be affected?
- More difficult to obtain data from EUDAMED
- Allied to EUDAMED questions
- UK databases

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Allied Regulation;

Not just the MDR…

- Environmental considerations (should be included as part of the ‘Withdrawl Bill’;
  - REACH
  - WEEE
  - RoHS
- Other legislation will need consideration;
  - General Product Safety
  - Machinery
  - Etc.,
- Change control!?

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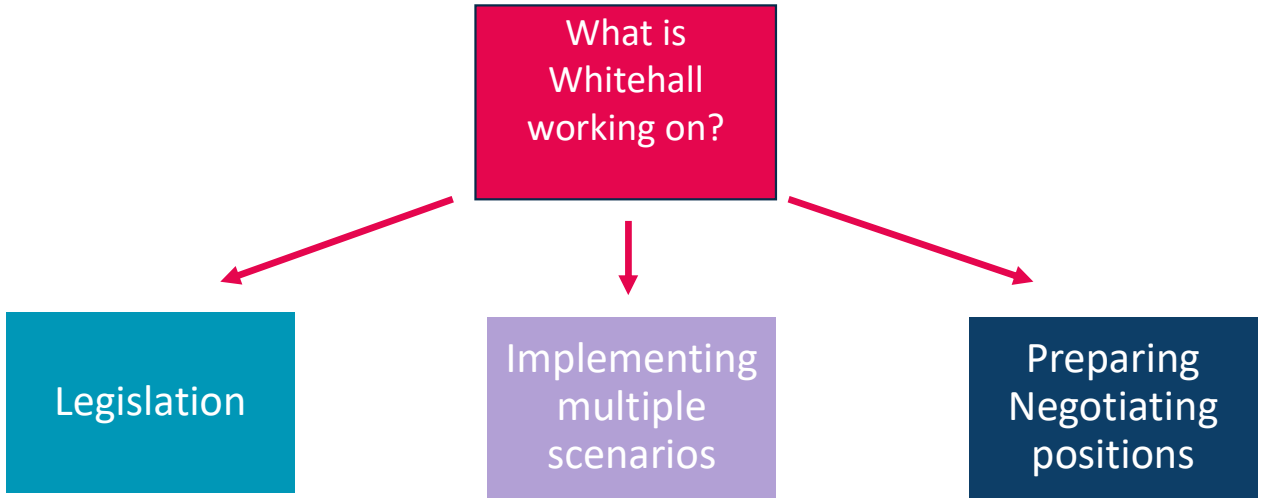
Challenges

Working with Whitehall



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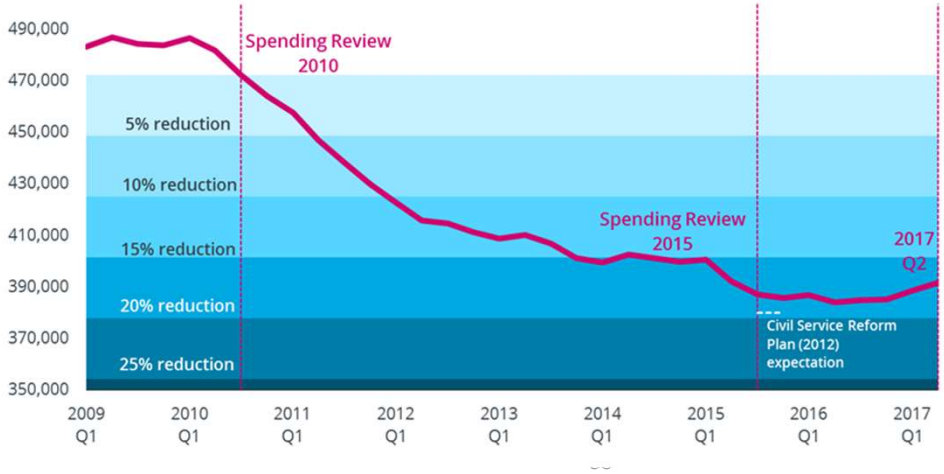
CHALLENGES

Working with Whitehall: Legislation

- Key piece of Brexit legislation: EU Withdrawal Bill
- Numerous other Brexit laws
- Huge volume of secondary Brexit legislation

All with the smallest civil service since WWII…



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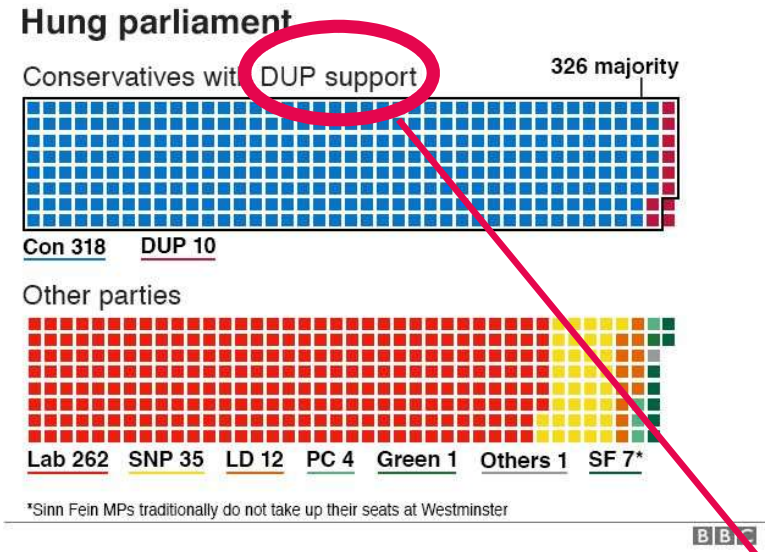
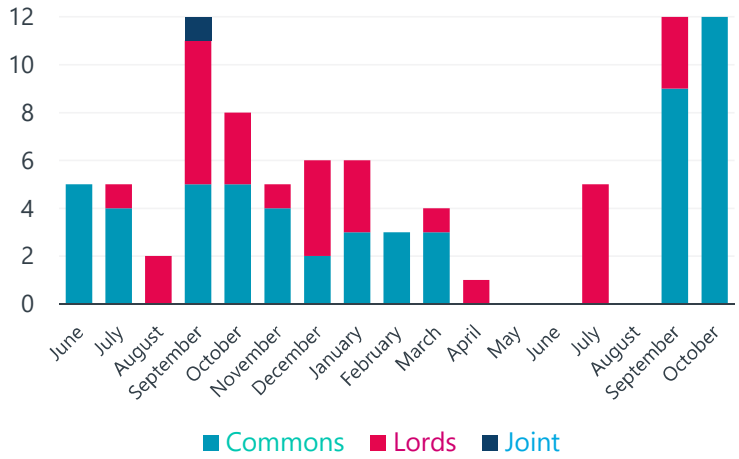
CHALLENGES

Working with Parliament…





The Irish challenge…

Medical Technologies

Conclusion;

It's easy to say, "Don't panic…"

"A woman's guess is much more accurate than a man's certainty."
— **Rudyard Kipling**, **Plain Tales from the Hills**

"...but in this world nothing can be said to be certain, except death and taxes."
— **Benjamin Franklin**,

"I believe that we do not know anything for certain, but everything probably."
— **Christiaan Huygens**,

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MEDEC RA Update: Key Priorities, Issues and Opportunities to Partner

Diana Johnson
Vice President
Regulatory Affairs
MEDEC

Diana Johnson

Diana is a Chartered Biologist and currently the Vice-president of Regulatory Affairs at MEDEC, Canada's national association of medical technology companies. In this role, she represents MEDEC members in the areas of domestic and international regulatory affairs, promoting global harmonization both directly, and together with other trade associations.

Prior to joining MEDEC in April 2018, Diana was an active industry regulatory affairs professional with 30 years' experience with prescription and over-the-counter drug products, including over 14 years' experience with Medical Devices, Natural Health Products, and Cosmetics, and 5 years leading a Clinical Research team. During this time, she held positions of increasing responsibility within companies such as Glaxo Wellcome, Pharmacia and Alcon and received several awards as a manager and collaborator.

Diana holds a B.Sc. (Hons) in Applied Biology and, before moving her family to Canada, was involved in drug development activities for the world-wide registration of new veterinary products.

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LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

MEDEC: Regulatory Affairs Update

Key Priorities, Issues, and Opportunities to Partner

Outline

- MEDEC
  - Structure and function
  - Current priorities
- Current issues
- Market Authorization Project with Health Canada

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LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

MEDEC – who are we?

- The only national medtech trade association

  Self funded

- ≈ 150 members from across all segments of industry

- Over 40 years of history

- Advocacy and membership support

  MEDEC advocates for Canada's medical technology companies in accelerating patient access to leading edge, innovative technology solutions that yield valuable outcomes

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LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

Strategic Imperatives

- Foster Growth & Leadership Profile of Canadian Medical Technology Eco-System
- Promote Strategic Procurement & Funding Reforms
- Engage the Voice of Clinicians/Patients in Advocating for Access to Innovative Technologies
- Shape Data & Informatics Policy to Enable the Enhancement of Healthcare in Canada

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Organization

- **Committee-driven**
  - Issues-based Committees and Working Groups: Regulatory Affairs, Procurement, HTA, Innovation, GDSN…
  - Regional Committees: Quebec, Ontario, West
  - Sectoral Committees: Lab/Dx, Hospital to Community, Vision Care, Cardiovascular, Orthopaedics, Imaging, Wound Care…
- **National Presence**
  - Central office in Toronto
  - Satellite office in Montreal to manage Quebec advocacy
  - Remotely-based VP to cover Western Canada
  - Additional connectivity through MOUs with regional Life Sciences organizations

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Update on National Issues and Opportunities

- Champion Shift from Volume to Value-based procurement
  - Ontario Supply Chain Review panel & Office of Chief Health Innovation Strategist
  - Alberta Innovates Health Solutions - Strategic Clinical Networks
  - Surrey Innovation Blvd. & Nova Scotia
  - Conference Board of Canada & Project with MedTech Europe
  - Research & Paper: Challenges and opportunities for the adoption of innovative medical technology in Canada
  - Changing the procurement dynamics in Quebec
    - MSSS: volume consolidation strategy is firmly entrenched
    - Treasury: open for value, Bill 108 on public markets management
    - Life Sciences Sector Working Group

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Update on issues and Opportunities (2)

- Collaborations with Clinicians / stakeholders re: advocating for value & adoption solutions
  - Most notably IVD, Orthopaedics, Wound care, Vision care & Hospital to Community (Ontario)
- Regulatory Approvals – Timelines and Requirements

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Regulatory Affairs Specific Areas of Focus

- Addressing the barriers:

  Market authorization timelines, Cost recovery, Vanessa's Law, Data transparency/CBI

- Harmonization initiatives:

  IMDRF, Regulatory Cooperation Council (US-Canada), CETA (Canada-EU) and with GMTA/DITTA

- Issue-specific projects:

  UDI, cybersecurity, digital health, electronic documentation

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Regulatory Affairs Committee(s)

- Main and Steering Committees

Sub-committees focus on specific issues	
Pre-Market Licensing	Post-Market Vigilance
eHealth initiatives	Health Canada Guidance Documents
In Vitro Diagnostic Devices	Diagnostic Imaging
Global Regulatory (IMDRF)	Regulatory Cooperation
Transparency Task Force	Education/Training

- Meet with Health Canada at formal Bilateral Meetings twice yearly

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Issues Addressed Recently

- Cost Recovery (with Federal Affairs Committee)
  - Provided written comments and held multiple meetings with Health Canada (Deputy Minister and RORB)
- Draft ITA Guidance – comments supplied
  - Health Canada indicated comments are being incorporated and their process being re-evaluated
- GMDN
  - Jointly supported Ivey Research and provided feedback to MDB
- MDSAP
  - Provided comments at multiple stages; hosted webinars (recordings available)
- IMDRF
  - ToC and Personalized Medical Devices – provided feedback

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Issues Being Addressed

- R2D2: Improving the Regulatory Review of Drugs and Devices
  - Public release of clinical information
  - Building better access to digital health technologies
  - Early pre-submission scientific advice for medical devices
  - Strengthening the use of real world evidence and regulations for medical devices throughout product lifecycle:
    - better use of RWE for regulatory decision making
    - more attention on the post-market aspect of medical devices to improve regulatory oversight
    - more proactive surveillance model for monitoring the safety and effectiveness
    - enhanced ability to manage identified safety risks for medical devices
  - Renewal of the Special Access Programme

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Issues Being Addressed (2)

- Regulation and Health Innovation
- Mandatory Reporting of Serious Adverse Drug Reactions and Medical Device Incidents by Health Care Institutions
- Reducing approval times
  - Health Canada initiatives
  - Joint projects

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Market Authorization Project

- **Project Goal (April 2017)**
  - To achieve the clarity and alignment necessary for MEDEC and Health Canada to work together to improve overall market authorization time

- **Project Scope (May 2017)**
  - New applications, amendments: Class III, IV; ITAs
    - Improvements to also apply to Class II applications, amendments

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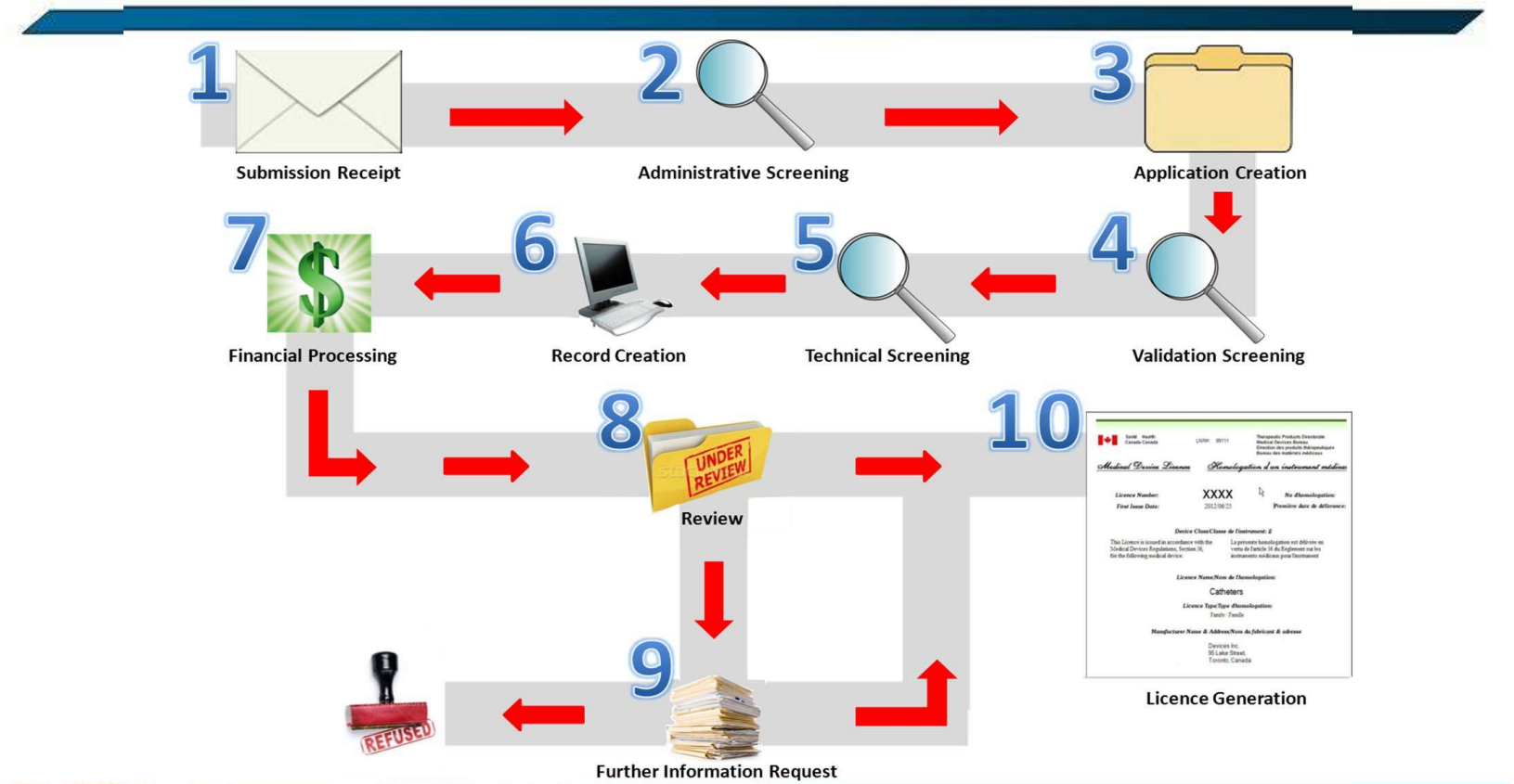
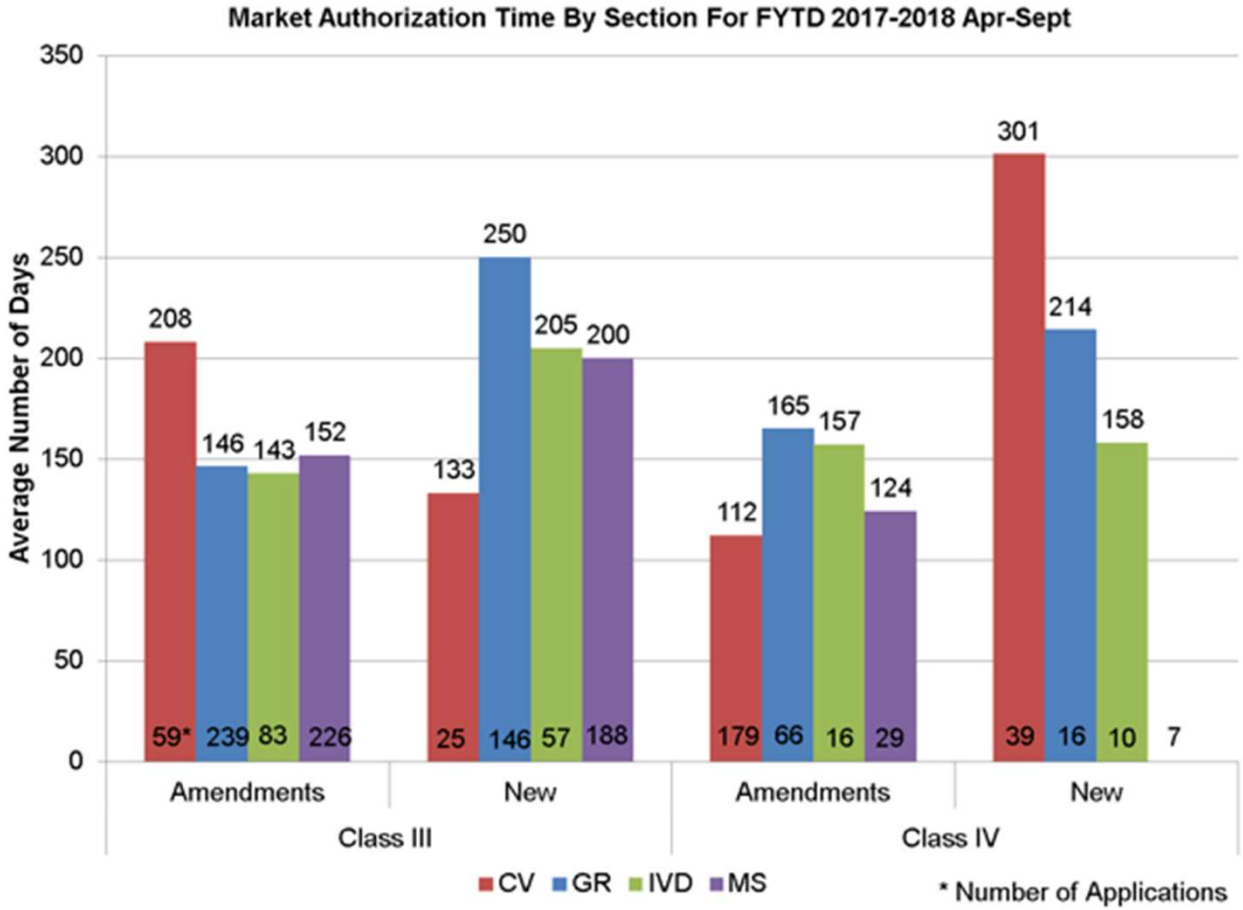
Application Management Policy – Class III & IV Devices



Source: Health Canada

Market Authorization Time



Submission Quality Project

- **Project Goal (Sept 2017)**
  - Gather data for a root cause analysis in order to formalize a joint work plan (MEDEC, Health Canada) that will address the issues that are delaying overall market approval times for new applications, amendments (Class III, IV) and ITAs

- **Submission Quality Project Survey (Oct – Nov 2017)**
  - Identify organizations/individuals interested in being involved in the Project
  - Have representation across classes/sections
  - Identify what data is currently being tracked
  - 28 individuals responded to the survey
  - 20 agreed to be part of the Project Team

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Submission Quality Project

20 Participating Companies			
Bard	Baxter	Baylis	BD
Biotronik	Boston Scientific	ConMed	Cook
Edwards	J&J	LifeScan	Medtronik
Ortho-Clinical	Philips	Roche	Siemens
Smith & Nephew	Stryker	Canon (Toshiba)	Zimmer

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Background: Submission Quality Project

- **Data Collection (Jan to Mar 2018)**
  - MEDEC tool to collect submission data information
  - Each company was asked to provide information on 5-10 submissions
  - Focus on the ones that didn't go according to plan
  - Ideally want submissions from 2017 - not before 2016

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Submission Quality Project - Summary

	Total	CV	GR	MS	IVDD
# of companies*		**9**	**12**	**6**	**3**
# of submissions	**135**	**34**	**50**	**36**	**15**
Class III - New	38	0	19	11	8
Class III - Amendments	63	7	28	24	4
Class IV - New	12	10	1	0	1
Class IV - Amendments	22	17	2	1	2
# with SD	**75**	**18**	**32**	**18**	**7**
% with SD	56	53	64	50	47
# with AI	**101**	**23**	**39**	**27**	**12**
% with AI	75	68	78	75	80

* Companies provided data across multiple divisions

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Top Reasons for Screening Deficiency - Summary

	Total	CV	GR	MS	IVDD
# Submissions with SD	**75**	**18**	**32**	**18**	**7**
Admin/labelling	**12**	1	6	4	1
Admin/misc.	**9**	1	7	0	1
Tech/clinical studies	**9**	3	4	1	1
Tech/marketing history	**8**	2	1	5	0
Tech/physical and mechanical tests	**8**	2	1	5	0
Admin/application forms	**6**	2	4	0	0
Admin/submission completeness	**6**	2	2	1	1
Tech/labelling	**6**	2	2	1	1

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Timing from Submission to Screening Deficiency

	# of submissions with data*				
	Total	**CV**	**GR**	**MS**	**IVDD**
	66	**16**	**27**	**16**	**7**
0-15 days	**12 (18%)**	2	7	1	2
16-30 days	**27 (41%)**	5	13	7	2
31-45 days	**18 (27%)**	7	5	5	1
> 45 days	**9 (14%)**	2	2	3	2

* Not all companies were able to provide data for "time from subm. to SD"

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Top Reasons for AI Requests – Summary

	Total	CV	GR	MS	IVDD
# submissions with AI	**101**	**23**	**39**	**27**	**12**
Tech/labelling	**45**	9	11	20	5
Tech/physical and mechanical tests	**39**	14	15	10	0
Tech/marketing history	**25**	10	10	3	2
Tech/clinical studies	**16**	11	3	1	1
Tech/software	**16**	3	11	0	2
Tech/sterilization	**10**	2	8	0	0
Admin/device description	**10**	0	10	0	0

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Health Canada/MEDEC

- MEDEC team met with Health Canada May 24, 2018
  - Submission Management and Division Heads
  - Presented our data and discussed potential causes and solutions in a collaborative manner
  - Agreed that some ongoing projects may help
    - Marketing history template – recently posted on MEDEC website
    - E-learning modules – being developed as part of R2D2
  - Areas for immediate attention/further effort:
    - Tech/labelling – providing specific examples to Health Canada
    - Summaries – help with meeting reviewer expectations

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Submission Quality Project - Next Steps

- Formalize joint work plan to address top reasons, actions, timelines, responsibilities (July)
    - Tech/labelling – providing specific examples to Health Canada
        - Whether IFU must be considered a promotional document is being reviewed by Health Canada
    - Summaries – considering webinar of best practices to meet reviewer expectations and/or template(s)

- Implement and monitor joint work plans (July-Dec)

MEDEC
CANADA'S MEDICAL TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

In Summary

- MEDEC advocates for you on wide range of issues
  - Domestically and internationally
- Many changes are coming from Health Canada
- Stakeholder input is vital to making effective changes
- The MEDEC RA Committees are very engaged with Health Canada initiatives

MEDEC
CANADA'S MEDICAL TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

Thank you!

For further information and to get involved contact: djohnson@medec.org

MEDEC

CANADA'S MEDICAL TECHNOLOGY COMPANIES

LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIES MÉDICALES

BREAK

Medical Device Bureau

David Boudreau
Executive Director
Medical Devices Bureau
Health Canada

David Boudreau

David Boudreau has a biochemistry degree and a chemical engineering degree (with honour) from the University of Ottawa. Once he completed his studies, he worked for three years at i-STAT, as a Process Engineer in the manufacturing of medical devices for blood tests. In 2004, he joined the Patent Office at the Canadian Intellectual Property Office (CIPO) as a Patent Examiner, where he specialized in diagnostic methods and devices.

In March 2010, he joined the Office of the Commissioner of Official Languages (OCOL), as Special Advisor. In January 2014, he was promoted to the position of Assistant Director, in charge of external audits and evaluations. In November 2014, he came back to the Patent Office as Director, where he was responsible for a group of 145 employees in the sectors of Quality, IT, Training and Operations. In January 2018, he has taken on new challenges at Health Canada, as Executive Director of the Medical Devices Bureau.

Health Canada Santé Canada

Canada

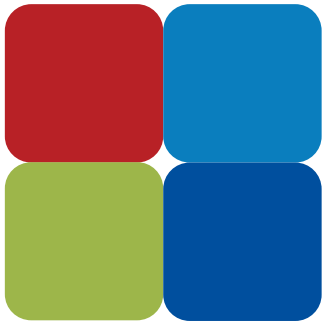
Update – Medical Devices Bureau

David Boudreau

Executive Director, Medical Devices Bureau

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

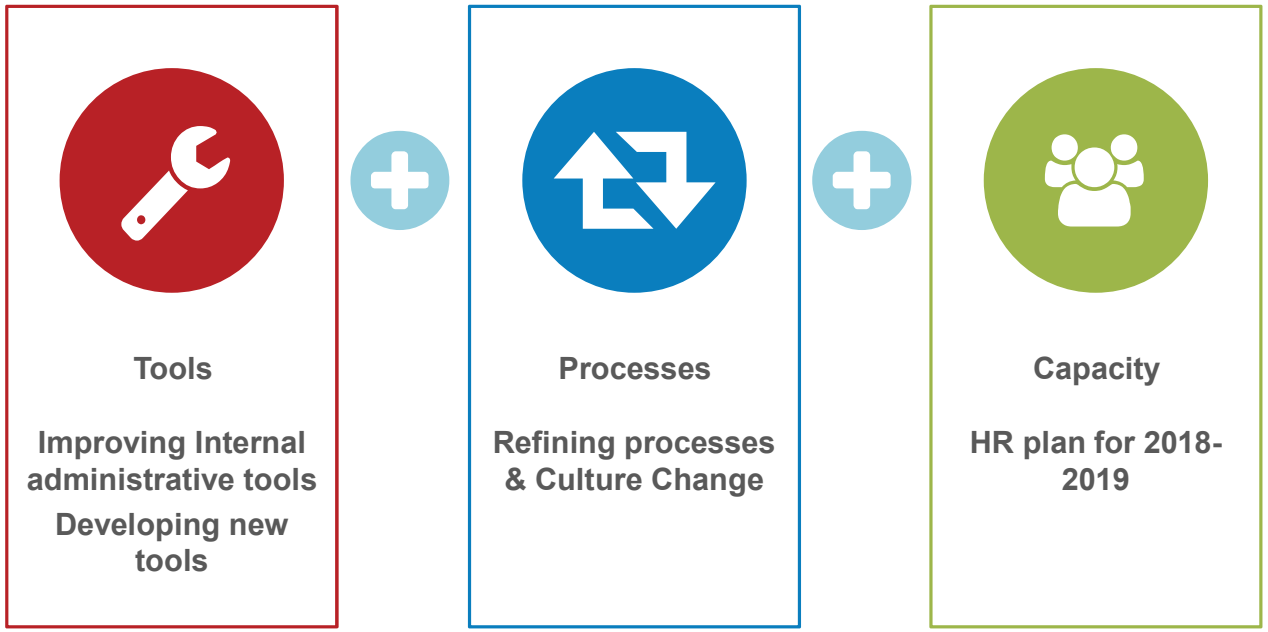
1. Reduction of audit duration for SMEs (meeting the criteria)
2. Allowing manufacturers to transition to MDSAP while carrying-on with their existing certification cycle under CMDCAS

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%		

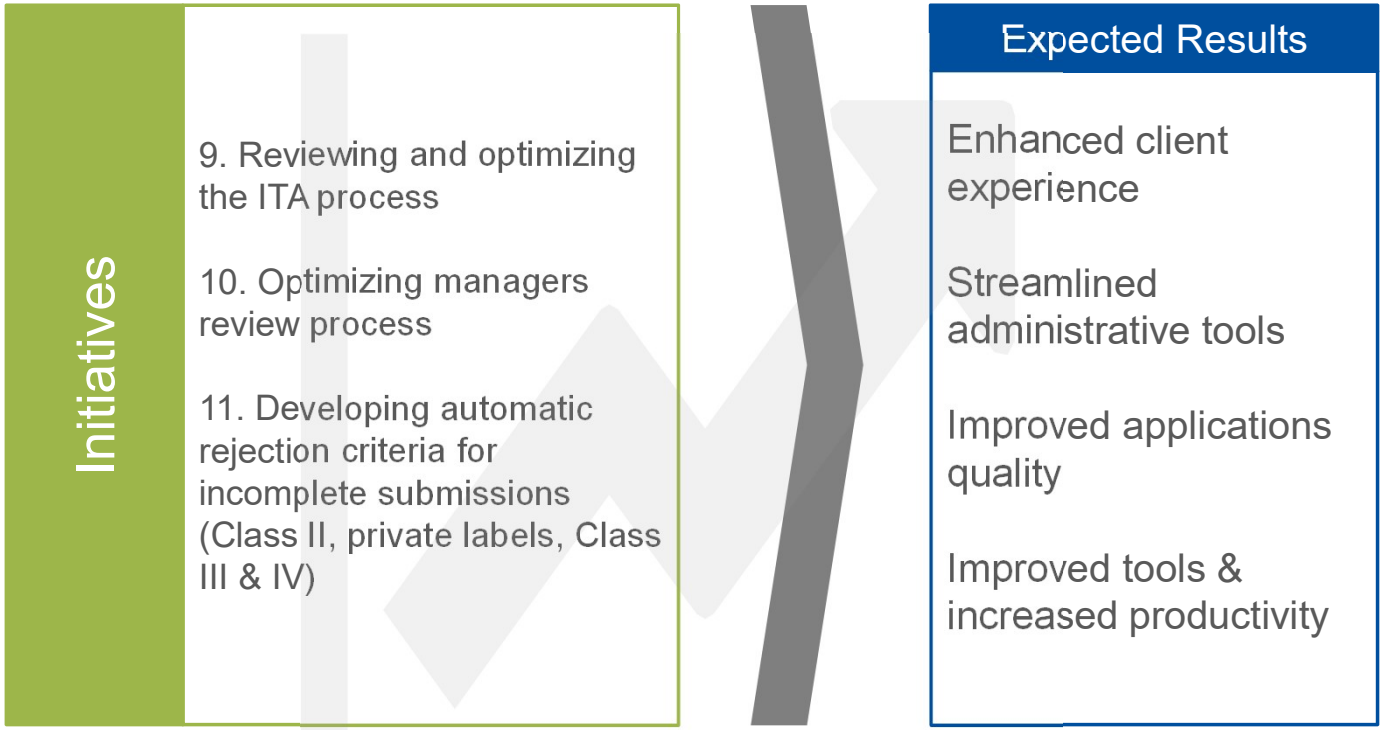
MDB – Performance Improvement Plan

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

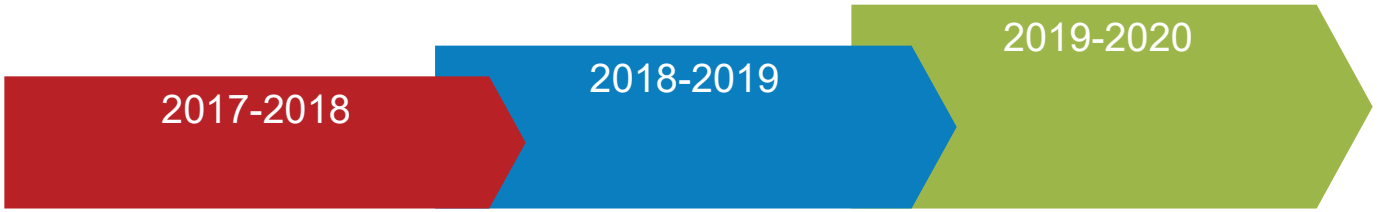
Implementation Spring 2019

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?

Contact - David Boudreau

Executive Director / Directeur Exécutif

Medical Devices Bureau / Bureau des matériels médicaux

David.Boudreau@Canada.ca

613-952-7125

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

Health Canada Update: MDSAP

Frederic Hamelin
Manager, Quality Systems Section
Medical Devices Bureau
Health Canada

Frederic Hamelin

Frédéric Hamelin has been with the Medical Devices Bureau since 2002 and is currently the Manager of the Quality Systems Section, and the Vice-Chair of CSA Z.289 – Medical Devices. He participated in the development of ISO 13485:2016 and was an active member of GHTF Study Group 4 from 2006 until disbandment. He is currently a subject matter expert and Assessor representing Canada in the MDSAP Consortium.

Health Canada Santé Canada

Canada

Health Canada MDSAP Update

Frédéric Hamelin
Manager – Quality Systems Section
Medical Devices Bureau

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Overview

1. New MDSAP Transition Guidance
2. Audit Duration Adjustments
3. Status of Transition
4. 2018 MDSAP Forum Stakeholder Day
5. Questions

New MDSAP Transition Guidance

Notice
April 4, 2018

In light of stakeholder feedback

Health Canada announced modifications to the transition process

Enforcement discretion for audits in 2018

Manufacturers to submit a valid MDSAP certificate by December 31st, 2018

- Health Canada will not take enforcement action against manufacturers that can demonstrate that they have undergone an audit
- We are sensitive to the challenges of both scheduling the audit and issuing the certificate

New MDSAP Transition Guidance

Notice
April 4, 2018

In light of stakeholder feedback

Health Canada announced modifications to the transition process

Transition to MDSAP through surveillance audits

Manufacturers must meet the following conditions:

- initial or re-registration audit after 2016/01/01
- certificate under CMDCAS valid until 2018/12/31
- Maintain a valid ISO 13485 certificate as of 2019/01/01

Manufacturers must provide the following:

- Certificate under CMDCAS valid until 2018/12/31
- Valid ISO 13485 certificate issued after 2016/01/01
- MDSAP Surveillance Audit Confirmation Notification

OR

evidence of arrangements to undergo MDSAP audit

Will allow manufacturers to maintain their existing certification cycle

Audit Duration adjustments

Notice
April 27, 2018

In light of stakeholder feedback

Health Canada & MDSAP Consortium announced revised procedure for audit duration calculations

Audit duration adjustments for SMEs

New procedure in effect - June 11, 2018

- AOs responsible to make the adjustments on a case-by-case basis as applicable

To be eligible, a manufacturer must:

- Have 100 or fewer employees
- Make lower-risk products (typically class II)
- Use only simple design and manufacturing processes using commonly available materials
- Have a good history of compliance to 13485

The adjustments are on a sliding scale and range from 5% to 42%

Audit Duration adjustments

Notice
April 27, 2018

In light of stakeholder feedback

Health Canada & MDSAP Consortium announced revised procedure for audit duration calculations

Revised Surveillance Audit Guidance

New procedure in effect - June 11, 2018

MDSAP Consortium revised surveillance audit requirements

- Standardize surveillance audit requirements
- Some MDSAP tasks not applicable during surveillance audits
- Re-focuses and slightly shortens surveillance audits

Status of Transition – on track

MDSAP Survey

December 2017 - about half of companies planning to transition expected to do so in the second half of 2018

2200 facilities registered with MDSAP

Approximately 240 MDSAP certificates received by Health Canada to date

- long wait times between audits and certificate issuance
- certificates received by manufacturers but not submitted to HC?

Continue to monitor

MDSAP will bring:

- greater alignment of rules with regulators in other jurisdictions
- important benefits to manufacturers operating in multiple markets

2018 MDSAP Forum Stakeholder Day

May 9, 2018

Participating Manufacturers invited to MDSAP Stakeholder Day

- Attended by AOs, RAs, and manufacturers
- Information provided on changes to program and regulations
- Workshops with manufacturers
- Question and Answer Session

Output

- Material available on MDSAP website
- Scroll down to heading "2018 MDSAP Stakeholder Day Presentations"

Questions?

Contact – Frédéric Hamelin

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613-954-0387

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

Lunch
(networking)