MEDEC

CANADA'S MEDICAL TECHNOLOGY COMPANIES
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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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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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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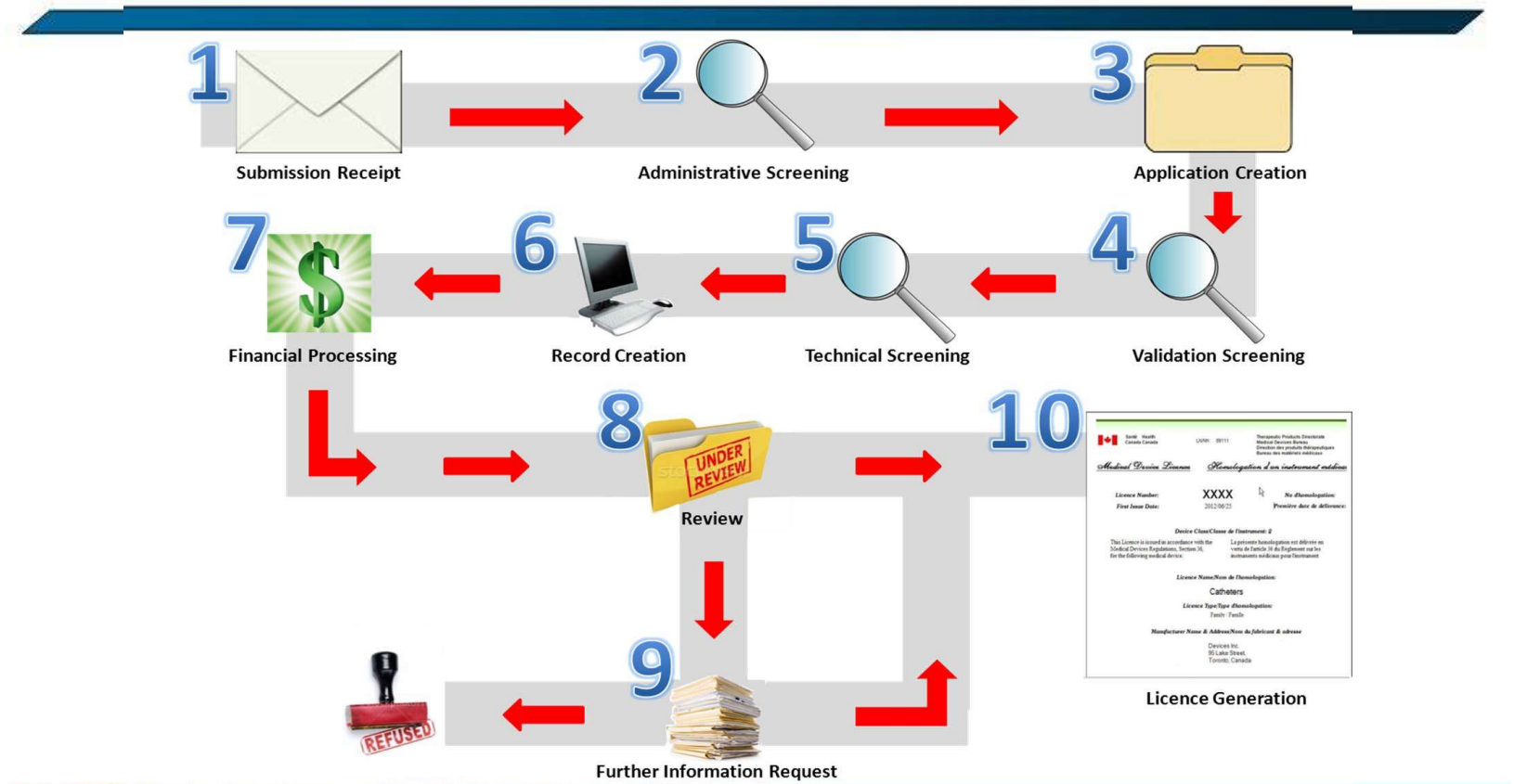
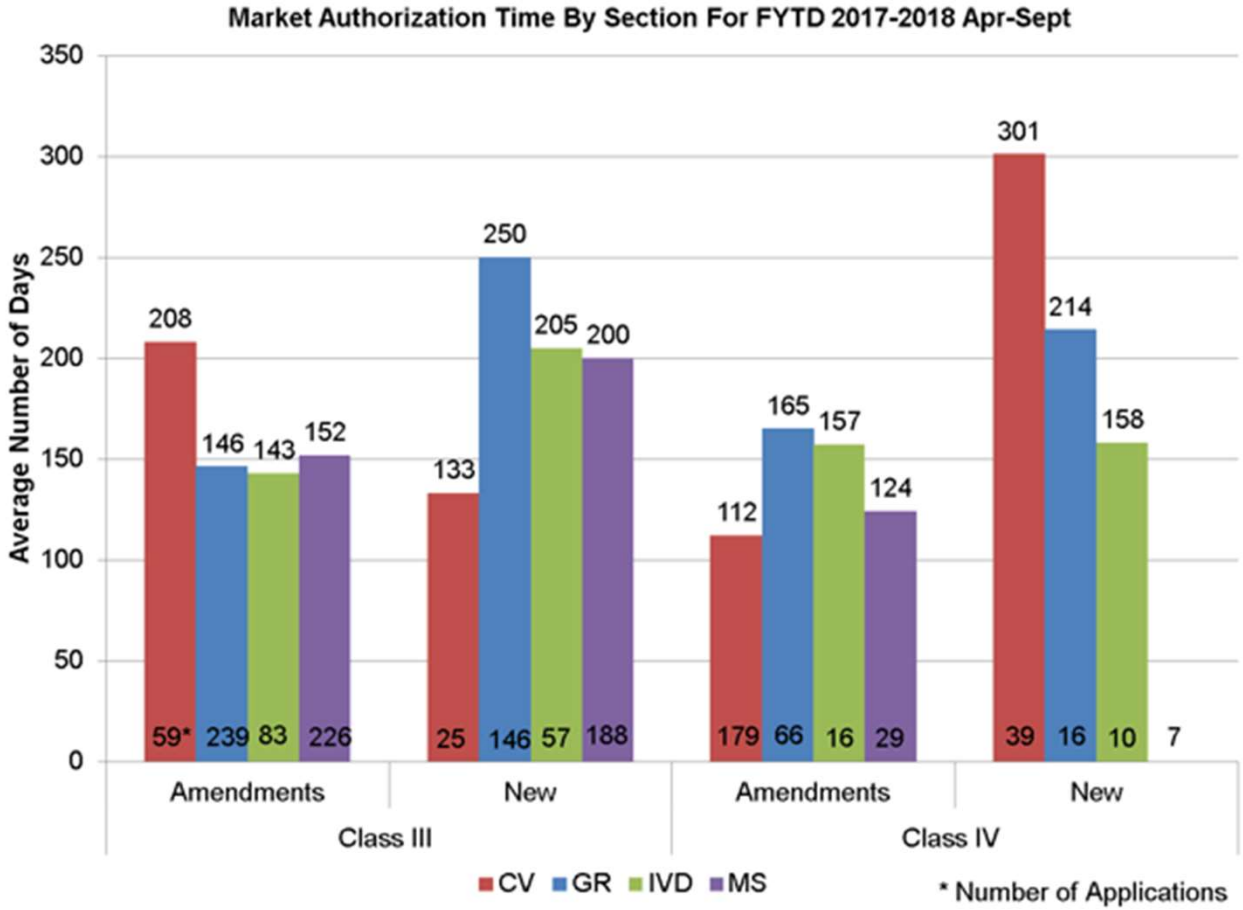
Application Management Policy – Class III & IV Devices



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)

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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

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Thank you!

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

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