MEDTECH CANADA ADVOCACY AND COMMITTEE UPDATE

FEBRUARY 2024

This document is background for the Medtech Canada Board of Directors and for Medtech Canada members on the association's actions and go-forward planning. It is produced quarterly and encompasses both Medtech Canada's new initiatives and updates to ongoing initiatives and activities over the last quarter.

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1. New, Emerging, or Priority Updates

A. Building Ontario Businesses Initiatives (BOBI) & Updated BPS Directives

- In 2022, the Ontario government introduced the Building Ontario Businesses Initiative (BOBI), an effort to bolster the province's economic growth and enhance supply chain resilience.
- This legislation mandates that public sector entities prioritize Ontario businesses when procuring goods and services below a specified threshold amount.
- **Scheduled to come into effect on April 1, 2024,** the BOBI Act will be applicable across all public sector procurements, including **hospitals,** ministries, agencies, school boards, universities, and various other institutions.
- In terms of how the government is defining an Ontario business, here is the official definition:

Ontario business:

2. (1) A business that meets the following requirements is considered to be an Ontario business for the purposes of the Act:

1. The business is a supplier, manufacturer or distributor of any business structure that conducts its activities on a permanent basis in Ontario.
2. The business either,
   i. has its headquarters or main office in Ontario, or
   ii. has at least 250 full-time employees in Ontario at the time of the applicable procurement process.

Threshold:

4. For the purposes of section 3 of the Act, the prescribed threshold amount is the following:

1. For a public sector entity that is a government entity,
   i. in respect of a procurement process for goods, $30,300, and
   ii. in respect of a procurement process for services, $121,200.

2. For a public sector entity that is a designated broader public sector organization,
   i. in respect of a procurement process for goods, $121,200, and
   ii. in respect of a procurement process for services, $121,200

- The Ontario Government also released updated BPS Procurement Directives which came into effect on January 1, 2024
- The updated directives can be found here: Broader Public Sector Procurement Directive (ontario.ca)
- Medtech Canada is planning on hosting a webinar to help members better understand the updated BPS Procurement Directives
- In the meantime, questions can be directed to Amy Swanson, VP Ontario at aswanson@medtechcanada.org

B. Health Canada Consultation Report: Improving Access to Health Products in Canada

- Health Canada recently released a report on responses to a consultation it hosted focused on identifying the challenges and possible solutions for building a resilient supply of drugs and other health products (including medical devices) in Canada.
- Medtech Canada represented our industry through this consultation and our association was recognized as an Advisory Committee member in the report (see Annex A).
- Many of our key points are being represented in the report.
- Below are the five overarching themes in the report, along with key highlights from those sections that are pertinent to our industry and align with our advocacy positions:
    - **Improved communication and transparency**
        - *"Industry stressed the importance of information sharing and protecting proprietary information."*
    - **Agile regulatory toolbox**
        - *"Stakeholders also suggested making improvements to existing shortage reporting requirements and planning to prevent shortages. We were cautioned not to impose undue burden on industry. Stakeholders also stressed that streamlining regulations and making them more in line with the international community would encourage a more competitive and diversified Canadian market."*
    - **Greater supply chain visibility**
        - *"Stakeholders wanted improved inventory level data at different points of the supply chain to better anticipate shortages."*
    - **Enhanced response to supply and demand**
        - *"Stakeholders stressed that domestic manufacturing should be strengthened. We also heard that procurement and contracting practices could support health product supply resilience by prioritizing security over price and by contracting with multiple suppliers."*
- Regarding next steps, Health Canada indicated the following:
    - *"For the next phase of our work, we will focus on developing a plan that will consider this input. To improve the resilience of Canada's health product supply chain, we will consider:*
        - *the roles and responsibilities of all the partners who have a role to play*
        - *initiatives already underway across the federal government"*
- Read the full report here.
- A special thanks to Medtech Canada's Shortages Working Group for contributing to our understanding of these issues.
- If you have any questions, please contact Medtech Canada's VP Federal Affairs & National Strategic Partnerships, Raj Malik at rmalik@medtechcanada.org or Medtech Canada's VP Regulatory Affairs, Mia Spiegelman at mspiegelman@medtechcanada.org.

C. Pest Management Regulatory Agency (PMRA) Update

- In December of 2022, DIAC, a Medtech Canada member, brought to our attention new regulations that had been implemented by the Pest Management Regulatory Agency (PMRA).
- These regulations were alarming as they would have impacted all Class 1 Medical Devices (where previously they had not been regulated by this agency).
- The impact was assessed to be severe: All Medical Devices (Class 1) that had been treated or included certain substances (regulated by PMRA) would have been found to be in none-compliance.
- The ETA for a get-well date (or compliance) was at best estimated to be 5 years.
- This would have impacted every-day devices such as masks / gowns and even certain IVDDs.
- Medtech Canada and specific members created a working group that tackled this concern as well as coordinated various engagement opportunities both with other association as well as with Health Canada and PMRA.
- We have happy to announce that after a year of focused work by the above-mentioned parties, PMRA has indicated to us in January 2024 that they intend to amend the regulations and propose the exclusion of Medical Devices completely (Class II-IV are currently already excluded).
- We have communicated the intent to our members and have requested (and are waiting) for the formal response form PMRA, which we will as well share with all.
- Please note that this change will take time as it needs to go through the regular pathway of regulatory change, however we expect this to pass in support from both Health Canada as well as Industry.

D. Canada's Regulatory and Quality Conference 2024, April 23 & 24, Ottawa

- This year's conference is shaping up to be a trendsetter!
- It will be hosted at the John G. Diefenbaker Building in Ottawa and will provide technological capabilities to host a fully hybrid conference.
- This two-day event is expected to run from 8:30-4:30pm on both days as it will be packed with important news both from Health Canada as well as Industry updates.
- Our planned speakers will cover topics related both to Pre-Market and post-Market such as eSTAR, UDI, MDEL audits and trends as well as MDSAP.

2. Core Committee Updates

A. Procurement & Supply Chain

Procurement and Supply Chain Operating plans for 2024

- Initial discussions about the specific operating plan strategies and tactics for 2024 occurred at the December 8th committee meeting and the draft plan has been finalized by Rob Pankhurst and Pamela Robertson. Following Board review, further discussion and detailed tactical plans for each working group will be confirmed with the new Co-Chairs Brenda Loft (3M) and Carile Staveley (Fujifilm SonoSite) and work will begin following the Feb 14,2024 committee meeting.
- The 2024 plan focusses on MTC strategies 2, 4 and 5.
- Key deliverables will include:
    1. robust review of all collaterals and creation of a user friendly, easy access approach for members to leverage a "national procurement toolkit."
    2. refresh of Escalation Process, guidelines, and database
    3. jurisdictional scan of the Canadian landscape for health care delivery and procurement structure. N.B. This will need to be a dynamic document/ portion of the website as constant change is expected in these areas.
    4. advocacy and creation of alliances to build member engagement e.g., desired revisit of National Supply Chain Collaborative to fill HSCN gap, renewed alliances with CCHL, Supply Chain Canada, all procurement organizations, and national groups like the Conference Board of Canada.
    5. focus on liaison with regional and sector committees to ensure consistency of approach and messaging.
    6. continued member education on VB healthcare, supply, procurement, and category management.
- Working groups within the committee will be struck for:
    a. Whitepaper and/or messaging specific to what measurable improvements have been created by advanced procurement methodologies, initiatives, data / metrics / scope i.e., best practices perspective.
    b. Toolkit
    c. Escalation process update
    d. Speaker series insights and liaison
    e. Targeting and priority setting for partnership and liaison potential

B. Regulatory Affairs

Health Canada

- Our Bilateral Meeting with Health Canada took place on November 9th, 2023. There were a couple of topics that were not discussed at that time due to the volume of items that were brought forward and the time constraints for the meeting. We are planning to meet with Health Canada this year on one of the topics as the other one (PMRA) has since been resolved.
    - We will meet with Health Canada on February 9th regarding third party servicing.

- We have engaged health Canada on re-starting the "Manufacturer Days" which is a training opportunity for Health Canada – industry presents to them new technologies to assist with the regulatory review process.
    - As this evolves, we will maintain the members updated and seek engagement to support this initiative.

Closed Consultations / Workshops / Working Groups:

- Our members have participated and submitted feedback /consultation on the following areas of interest:
    - PMRA – Due to resolution of this concern, this working group is closed. When the consultation comes up (Gazette I) we will send out a notice for members to join (expect Q3-4 2024)
    - SAC-DHT – Health Canada requested that industry speakers (members of Medtech) present to the Scientific Advisory Committee on Digital Health Technologies (SAC-DHT) their perspective on few topics related to Software, Machine learning etc. The Working group presented successfully to the committee in January and therefore this Working group is now closed.

Open Consultations / Workshops / Working Groups:

- PRCI – Public release of Clinical Information is an issue identified by Medtech Members. Members wish to discuss concerns around the release of confidential business information (which HC is now stating is not confidential). Members and Medtech representation met with PRCI on November 9th and will be further coordinating a working group to engage PRCI directly on a working session soon. This working group is ongoing – they plan to also present an update during the upcoming Medtech Conference in April
- PFAS (Joint with Environmental) – This is a newly created working group that worked on submitting a joint letter as well as individual letter around recent notices with the intent to limit PFAS in Canada. The concern is around lack of available alternates and the imminent risk to patients and Health care providers (due to the impact on the availability of Medical Devices should this pass without exempting Medtech products). We have successfully coordinated a meeting with Environment Canada and Health Canada which will be held on February 2nd. Medtech members will present to the government the impact of the potential new requirements on the healthcare industry.
- Plastics Labelling and Registry (Joint with Environmental) – Working group is actively working on responding to a consultation due on February 12th regarding new requirements to register plastics (volumes) on a yearly basis. This will impact almost all members of Medtech as both manufacturers, importers, and distributors (and even hospitals) may now require implementing a tracking and reporting mechanism.
- Shortages Working Group – members of the working group are participating in ad-hoc committee meetings where Health Canada, PTs and Industry are collaboratively working in creating common definitions that will help coordinate and communicated signals and shortages.
- UDI – members have been working on updating the 2021 position paper and have had great input. This will include updated information around global implementation and lessons learned. Following this paper, they will continue discussing approaches to communicate industry needs to Health Canada which the government prepares its plan for UDI implementation.
- Significant Change Guidance – Health Canada contacted Medtech Canada to organize a pre-consultation review of the draft guidance changes. IT was extremely informative, and Health Canada thanked our members for their guidance and feedback. We expect the formal Draft consultation to come out in the next few months. The Consultation has yet not been published.
- Near Patient IVDD Reclassification – some MedTech members have indicated interest in reaching out to Health Canada to request reduction in medical device classification of certain IVDDs. This working group is meeting to discuss approach and timelines as well as next steps.

Committee and Subcommittee work

- Ongoing work is underway to reduce / streamline inactive Sub-committees. We have now also absorbed the Regulatory Cooperation as well as the Digital Imaging into the main committee. Where consultations require that these groups be re-formed (in order to respond to consultations for example), this will be done in the form of a Working Group.

Webinars / Training

- New Webinars took place that took place:
    - From Paper to Progress: The Benefits of eQMS webinar (November)

3. Regional Committee Updates

A. Federal

General

- Medtech Canada will deliver its' pre-budget submission for Budget 2024 to the Department of Finance on February 9, 2023. A working group has been formed from members of the Federal Affairs Committee to review the 2024 pre-budget submission that was put forward by Medtech Canada to the House of Commons Standing Committee on Finance (FINA) on July 28, 2023. Our final recommendations are forthcoming.
- Our submission will be posted on the Medtech Canada website.
- Medtech Canada will explore opportunities presented by Budget initiatives as a part of our ongoing advocacy with the federal government.
- If you have any questions, please contact Raj Malik, Medtech Canada's VP, Federal Affairs & National Strategic Partnerships, at rmalik@medtechcanada.org.

Right to Repair / Bill C-244

- Bill C-244 completed Third Reading in the House of Commons on October 18, 2023, with all-party support and has now moved to the Senate. The Bill has completed First Reading in the Senate and is currently in Second Reading; there is no timeline for this Bill to begin Second Reading as it is a Private Members' Bill and does not take priority.
- We continue to prepare for Second Reading – we have connected with the Senator responsible for leading the Bill in the Senate (Senator Colin Deacon) as well as ISED. We will be meeting with Health Canada shortly and we are refining our outreach plan as we gain more information.
- Our working group remains active as we refine our strategy. Our 2-page Position Paper has been completed and will be posted on the Medtech Canada website shortly. We will now work to complete the Backgrounder document that will provide additional information for interested key stakeholders.
- Government consultations are planned for 2024; timing for these has not been released yet.
- ***If you have any questions regarding Bill C-244 or Right-To-Repair, please contact Medtech Canada's VP of Federal Affairs, Raj Malik (rmalik@medtechcanada.org)***

Vendor Credentialing Program (VCP)

- We continue to work closely with Accreditation Canada (AC)/Heath Standards Organization (HSO)
- HSO/AC remains committed to the sustainability of a national vendor credentialing program and has already confirmed its continued commitment to the maintenance of the current vendor credentialing program for 2023. HSO/AC continues to support the vendor community as needed.
- As such, HSO/AC will continue, as they have been doing since 2020, to support any vendors who would like to participate in attestation and have access to training offered in partnership with IMC. HSO/AC also continues to field on-going queries from the vendor community – both existing vendors who have already accessed the current vendor credentialing program, and new vendors who require access for quality improvement and business purposes. HSO/AC continues to fulfill these requests.
- An updated position paper is now available.

Bill S-211: Fighting Against Forced Labour and Child Labour in Supply Chains Act

- Canada's new Act on fighting against forced labour and child labour (Bill S-211) was passed on May 11, 2023, and comes into effect on January 1, 2024. Affected businesses must report by May 31, 2024, on specific details and steps taken in its previous financial year to help prevent and reduce forced labour.
- The purpose of Bill S-211 is to reduce the use of forced labour and child labour in supply chains by increasing transparency in these supply chains. Specifically, the bill imposes reporting obligations on government institutions and on certain private entities that produce or import goods or that control entities that do so. The Bill requires these reports to be public and proposes fines for private entities that make false or misleading statements in their reports.
- To increase awareness of this Bill among Medtech Canada members, the Federal Affairs Committee (FAC) had Bill S-211 as an agenda item for both the September and December quarterly meetings. Bill S-211 was also on the agenda for the December Procurement & Supply Chain Committee meeting. The guest speaker at the September FAC meeting was the Executive Director of the Trade Strategy and Responsible Business Conduct division of Global Affairs Canada.
- Several law firms have written on Bill S-211 (e.g., Gowlings, Torys, BLG, Bennett Jones, Dentons, Norton Rose Fulbright, etc.…). We secured Torys to present Bill S-211 to the Medtech Canada membership during a Speaker Series Webinar in January 2024. A recording of the webinar will be posted on the members only side of the Medtech Canada website (new section of the website coming soon).

B. Ontario

The Medtech Conference in Toronto, 2024:

- Planning continues for AdvaMed's Medtech Conference in Toronto (Oct 15-17, 2024).
- "Expressions of interest" have been requested as of December 2023 for space in the Canadian Pavilion as part of the Exhibit Hall.
- A webinar was held on Jan 16, 2024, regarding the "Call for Proposed Session Ideas". Attendees were walked through the process and criteria to submit a proposal to AdvaMed as part of programming content. The portal is open and accepting submissions until Feb 23, 2024.
- The Host and Local Committee continues to grow in terms of numbers with the first meeting to be held on Feb 20, 2024. This is a volunteer-based committee that will convene key medtech stakeholders as part of planning for The Medtech Conference.

Ontario Pre-Budget Submission Work Group:

- The deadline for submission of a Pre-Budget document to the Ontario Government was January 31, 2024.
- Members of the Ontario Committee were invited to join this work group to draft the recommendations on behalf of Medtech Canada.
- The portal allowed for a maximum of three recommendations:
    - Procurement Modernization in Health Care
    - Innovation Pathway for Medical Technologies
    - Ontario Life Sciences Strategy

Innovation Pathway Work Group:

- The Government of Ontario announced in the 2023 Budget that would be exploring an Innovation Pathway.

- The Innovation Pathway, "in collaboration with Supply Ontario, would review promising new innovations and provide funding to health service providers so they can procure the innovations across the health system".
- The Innovation Pathway could also help remove barriers to earlier adoption of new technologies by funding clinical assessments.
- The Innovation Pathway is still in its infancy and Ontario Committee members asked to create a work group to help frame a roadmap for the province as they continue to explore this initiative.
- The work group has met once and continues to craft the proposed framework which will be shared with the Ontario Committee for feedback upon completion of the draft.

C. Quebec

Medtech Canada Prebudget Submission - Québec

- In the process of producing Medtech Canada's QC Prebudget 2024 submission, the association held two working sessions to establish our priorities and recommendations for 2024.
- The tone of the document is written in a positive and collaborative way to provide solutions to the province.
- Key focus is "Patient First," following which we made multiple recommendations on Health and patient support (re. the new QC Health Agency, LabCandx, Bill 96), Government Administration (reducing red tape), and Economic Development (Life Science Strategy to be potentially renewed after 2025).

Bill 96: "An Act respecting French, the official and common language of Québec"

- January 10, 2024: Edited regulation was published; therefore, we have 45 calendar days to provide our recommendation for amendments.
- That said, the edits from the government were minimal (only a page and a half) and targeted business signage more than anything else.
- Amendment recommendations on a project of regulation must be linked/an edit to the article published.
- In the current case, since there are littlest elements published re: the key challenges for our industry, it will be challenging to use this as an opportunity to present our recommendations.
- We will be advocating for our recommendations, but it is important to note that it now being 2 years since the passing of the Bill and the main regulations being published, it will be very challenging to convince the government to make any major or material changes to Bill 96 and the corresponding regulations.
- Having said that, Medtech Canada has started discussions with both the Minister of French Language Office and the Minister of Health (Minister and Chief of Staff), to whom we are asking for support in requesting some flexibility for our industry.

Value-Based procurement KPIs

- Following the presentation that Medtech Canada made to the QC Treasury Board (TB)Senior Executives in Sept 2023, and follow-up discussions with those key players, we created a working group on value-based procurement KPIs.
- TB asked us to meet for a 3-hours working session at the end of February, to address how value-based KPIs can be applied (in detail with examples from other jurisdictions) in Quebec Province, more specifically through the CAG.

D. Western Canada

Alberta

- Since the last report to the board Medtech Canada members presented to the Alberta Diabetes Working Group at the request of the Government of Alberta on Monday January 12th. Recommendations focused on (a) patient access (b) pathways for new technologies (c) need for strategic partnerships.
- Alberta continues to pursue significant health-system restructuring with Medtech staff pursuing regular updates on the status of Alberta's four new healthcare entities (a) primary care, (b) acute care (c) mental health and addictions and (d) continuing care.
- Alberta Health is currently accepting submissions from health-sector stakeholders to help inform the development of the four entities noted above (this process is expected to take ~2 years and will require legislative changes). A working group is currently active to inform the development of a submission from Medtech Canada, Rob Pankhurst will be attending an in-person consultation meeting in Edmonton on February 20th and will present to Alberta Health at that time the contents of Medtech Canada's submission.
- Medtech Canada continues to enjoy positive working relationships with Contracting, Procurement and Supply Management (CPSM) staff at Alberta Health Services, although it is expected much of the work currently undertaken by CPSM will transition to a new entity called the procurement optimization office, which will be housed within Alberta Health – that office will be led by Jitendra Prasad. Efforts are underway to develop a working relationship with this new entity.
- Medtech Canada is partnering with Bio Alberta to co-host a panel discussion *"Canadian CEO Panel - Medical Technology and the Future of Health Innovation"* on March 5th. In addition to this panel discussion Medtech staff (Nicole DeKort and Rob Pankhurst) along with company representation will be meeting with the Alberta Ministers of Health and Innovation in tandem with this panel discussion.

British Columbia

- Since the last report to this committee Rob Pankhurst along with company members, met with Victoria Schinkel, Executive Director, Research, and Innovation Branch (B.C. Health) – discussion focused on the Health Technology Assessment process B.C. is using – officials from B.C. Health agreed to quarterly meetings and to share the results of a external program review of their HTA process, which was recently received at the time of our recent meeting. t
- Medtech Canada continues to enjoy a positive working relationship with PHSA, including quarterly meetings with purchasing leadership team members.
- For the information of Board members, Neil Maharaj (who may be familiar as he was previously a category manager for cardiac, capital, lab and diagnostic imaging at PHSA) has moved into a new "Vendor Relations Management" role at PHSA.
- Medtech Canada (along with company members) will be present at Life Sciences British Columbia's *Access to Innovation: powering life sciences innovation and sustainable economic growth* conference. This is a gathering of life sciences leadership from academia, research, government, healthcare institutions and industry.

Manitoba

- As Noted in the last update to this committee, a meeting request was sent to the New Manitoba Minister of Health in December 2023, unfortunately a reply was received in January 2024 noting that government could "not *meet with individual organizations due to procurement policy and the volume of requests".* This response speaks to a lack of understanding of the role of our industry association, so work is underway to

try to better inform the Minister's staff of the work of Medtech Canada, and our efforts to be a collaborative partner to health systems and ministers across the country.

- Medtech Canada has secured meetings with system leaders from the Winnipeg Regional Health Authority (CEO Mike Nader) and Cancercare Manitoba (Jim Slater, Director of Research and Administration, Cancercare MB), these will be scheduled in the coming weeks and will involve company members.
- On February 23rd a "lobby day" has been booked where medtech west co-chairs Aleina Spigelman (Roche) and Jen Cox (Medtrnonic) along with Rob Pankhurst, will meet with Federal, Provincial and Municipal elected officials for the purpose of informing them of Manitoba's "medtech footprint".
- On February 24th Medtech Canada will host company members at the Health Sciences Centre foundation Savor Gala in support of the Health Sciences Centre foundation (thanks to Medtech Board Member Lindsay Williams who is making the trip to Winnipeg to support this engagement).

Saskatchewan

- The association continues to enjoy a productive working relationship with 3S Health (Saskatchewan's shared services organization), while making efforts to strengthen ties to the province's health authority (Saskatchewan Health Authority)
- A working group has been struck to address access to endocrinology specialist physicians (and resultantly timeliness to access continuous glucose monitors/insulin pumps). Rob Pankhurst recently met with Ministry staff to advise them a submission would be coming on this topic, there was willingness from ministry officials to receive Medtech Canada's advice on this topic.
- A meeting in the second quarter of 2024 is being planned with ministry officials, currently in planning stages but intent will be to bring actionable items to the ministry to ensure concrete follow-up is possible.
- In January of 2024 the Saskatchewan medical association and government of Saskatchewan reached a tentative deal re: physician master agreement – details have not been released as the agreement is subject to a ratification vote but the government had been floating a "blended capitation" remuneration model that would provide for (a) base payment for a standard basket of services and (b) additional fee for service payments for services outside of the defined basket of services noted above.

4. Sector Task Force Updates

A. Digital Health

General

- Continued regular engagement with Canada Health Infoway, Digital Health Canada, Women's College & the Canadian Medical Association (CMA).
- The Digital Health Task Force will continue working with Ben King, Director of Digital Health and Innovation, Santis Health to develop a comprehensive advocacy strategy for our Tier 1 priorities. Tier 1 priorities reference issues that the Task Force should be proactively advocating reforms for. This can be done by defining a set of positions and seeking opportunities to promote these positions to governments across Canada. Tier 1 priorities include:
  - Adapting digital device regulatory approvals for a digital world
  - Digital-device data sharing
  - Value-based care
- The Task Force will also identify Tier 2 priorities, in which Medtech Canada will not be leading advocacy efforts, but instead will provide input and support to stakeholders that are better suited to lead on these topics. Currently identified Tier 2 priorities include:
  - Getting privacy right
  - Cybersecurity
  - Competition Law
- For the remainder of Q1, the intent is to focus on developing advocacy strategies for these topics.
- We aim to bring the plan forward to the committee in the first meeting of 2024 and begin execution of the strategies shortly thereafter.

B. Laboratory Medicine (IVD)

General

- LabCANDx, whose members include Laboratory Medicine professionals and executives, and suppliers – announced that it has come together to provide a common voice for Laboratory Medicine in Canada.
- LabCANDx continues its advocacy for investment in laboratory medicine (focus on more efficient and optimal delivery of health care) to address pandemic issues, the growing backlog of procedures and timely, equitable access to quality medical care.
- National advocacy campaigns activated April. First advocacy teams will target for Ontario and federal.
  - Working on appropriate to Lobby registration approach for LabCANDx.
- Pre-budget consultations for Ontario, Quebec, and the rest of Canada.
- Phase one outreach efforts focussing on requesting meetings with Ministers/Minister's Office federally, Ontario and Quebec. Phase two focusses on Ontario and Quebec and the rest of Canada.
- Conducted an update on Canada's state of readiness for Genomics. Don Huserap rented findings. More than 25 people in attendance.

- Joint commercial and Regulatory sub-committee created to work on aligning selected Point of Care Tests administered by HCPs to align with other jurisdictions (e.g., change classification of some tests from Class III to Class II.

C. Medical Imaging (Market Data Only)

- The task force continues to engage on its market data collection.

D. Orthopaedic

- The group is currently working on developing a 2024 operational plan.

E. Vision Care

- Task force exploring approaches to create greater public disclosure about provincial waitlists. Currently all provinces except Quebec have two sets of procedure waitlists (i.e., doctor [not published] and hospital [published]).
- Proposal to Canadian Ophthalmology Society (COS) to provide advocacy training to physicians which would have CPD credits is being reworked to be an industry sponsored event with credits. Meeting with COS to discuss next steps on Thursday, February 8 to develop action plan.
- Continuing to collaborate and support an updated National Vision Strategy. Bill C-284 a private members Bill, Judy Sgro, has unanimously passed third reading and now moving to senate. We offered to help and support in terms of critical issues and needs.
- A focus for 2023 is to help drive the adoption of HTA recommendations by provinces for vision care technologies. Plans being developed.
- Revised and updated strategic/operations plan for 2024.
- Had initial and follow-up meetings with IQVIA and CIP (potential suppliers) re Vision Care market data.
- Setting up speakers series events with key vision care groups.

5. Working Groups

A. List of Current Active Working Groups

- Medtech Canada members are welcome to participate in any of these initiatives by contacting Gurman Virk, Manager of Government & Stakeholder Relations at gvirk@medtechcanada.org

Working Group Name	Medtech Canada Lead(s)	Description of Activities
JOINT WORKING GROUPS		
Shortages Working Group	Raj Malik/Mia Spiegelman	Product shortages have now been an issue for many months. As a result, Health Canada has recently (Jan. 2023) convened a Shortages Multi-Stakeholder Committee composed of P/Ts and group purchasing organizations; Medtech Canada has also been invited to have a seat at the table. This working group will highlight key pressing issues and formulate messaging that the Medtech Canada representatives sitting on the Multi-Stakeholder Committee can take back to the Committee for further discussion
FEDERAL WORKING GROUPS		
Bill C-244 and Right to Repair	Raj Malik	This Bill amends the Copyright Act. While the original intent was to enable farmers to access software for purposes of repairs not done by the OEM, it then morphed into consumer goods such as iPhones and appliances. These amendments to the Copyright Act impact/enable the right to access software for the purposes of repair, which can be significantly impactful to the functionality of medical devices and patient health outcomes. This working group has made a written submission to the Standing Committee on Industry and Technology (Dec. 16, 2022) asking for exclusion of medical devices and has testified at Committee Hearings (November 14, 2022).
Federal Pre-Budget Submission	Raj Malik/Gurman Virk	This working group participates in the public 2024 pre-budget consultation by providing a written submission to the Federal Department of Finance.
ONTARIO WORKING GROUPS		
Innovation Pathway	Amy Swanson/Gurman Virk	This working group is focusing on developing a medtech framework for the implementation of an Ontario Innovation Pathway.
Wound Care	Amy Swanson	This working group is formerly the Wound Care Task Force, that is now being absorbed into the Ontario Committee.

WESTERN CANADA WORKING GROUPS		
Diabetes	Rob Pankhurst	This working group works to address Saskatchewan Endocrinology Access
Submission to Alberta Health re: System Challenges	Rob Pankhurst	This group is putting together a Medtech Canada submission to Alberta Health about health system transformation.
QUEBEC WORKING GROUPS		
RFP Templates (Gabarits)	Olivier Bourbeau	This group works with the government departments and stakeholders on improving and streamlining the RPF process (notably the SCAG), and to introduce new measures (ex.: inflation clauses, “trusted suppliers’ fast track”) supporting strategic procurement improvement, as well as innovation integration in the Quebec Health System.
Value-based procurement KPIs/Treasury Board Ministry	Olivier Bourbeau	This group works with the Treasury Board Ministry’s General Management (Sous-secrétariat aux marches publics, Direction générale de l’encadrement) on value-based procurement KPIs to be potentially implemented in Quebec Province, more specifically through the CAG.
Non-pharma diagnostic innovations integrations process	Olivier Bourbeau	This group works with several government departments and stakeholders, including the Innovation Bureau, INESSS, and researchers, to develop a streamlined process for the introduction of non-pharmaceutical innovations (especially diagnostic innovations for which the process is long and counts several barriers).
New diagnostic tests registrations	Olivier Bourbeau	This group works on finding solutions to provide to the government to facilitate and ease the diagnostic tests registration (inscription de nouveaux tests diagnostiques) in Quebec Province.
Wound care/Bandages access (Soins de plaie/Accès aux pansements)	Olivier Bourbeau	This group works with government departments and stakeholders to add additional wound care products on the Quebec reimbursement list (RAMQ medical exception list).

REGULATORY WORKING GROUPS		
Public Release of Clinical Information	Mia Spiegelman	Members have identified concerns in the release of clinical information that is now public on the Health Canada website.
PFAS Issues	Mia Spiegelman	Consultation submitted and letter of support with other associations around the request to increase regulatory oversight and reduce the use of PFAS where there is no know alternate safe ingredients with similar or better characteristics.
Flame Retardants	Mia Spiegelman	Similar to PFAS, but regarding ingredients in flame retardants
Federal Plastic Reg Recycled Cont and Labels	Mia Spiegelman	New consultation that will be coming up which will impact devices and drugs in that it will forbid the use of international labels with international symbols around plastics. Currently consulting on plastics registry
Significant Change	Mia Spiegelman	The Medical Devices Directorate is finalizing a draft of the updated Significant Change Guidance.
Near Patient IVDD Reclassification	Mia Spiegelman	Members working towards requesting from Health Canada to change the classification rules of IVDDs as they relate to Professional use IVDDs (keeping them as class 2)
UDI	Mia Spiegelman	Working on updating the Medtech White paper for UDI as well as support and guide HC in the implementation of UDI in Canada
MDEL Section 44	Mia Spiegelman	Ongoing work in regard to Section 44 of the MDEs – regulations were changed without industry consultation. Working with HC to reverse this change.