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Meeting Minutes

Meeting Title:	Regulatory Affairs Committee	**Date:**	December 6, 2022
Place:	Microsoft Teams Meeting	**Time**	9:30 am to 12:30 pm
Purpose:	Regular Meeting		

Present:

Greg Leblanc, Cook Medical (Chair)	Catherine Matthews, Edwards Lifesciences
Aniline Soco, Abbott	Mary Semplicio, Advanced Sterilization Products
Lori Burns, Novocure	Christine Davis, Stryker
Corinne Delorme, Nexialist	Debbie Spence, Somagen
Shirley Furesz, TPI Reg	Linda Tremblay, Johnson & Johnson Medtech
Jessica Danti, Canon Medical	Marisa Petrielli, Consultant
Irma Vargas, 3M Canada	Janice Wright, TPI Reg
France Cadoret, Christie InnoMed	Joe De Croos, Molli Surgical
Vivek Patel, Zimmer Biomet	Kerri Austin, ICON
Eric Parent, Bio-Rad Diagnostics	Santina Pucci, Christie InnoMed
Laura Gillis, Stryker	Sophia Chin, Cochlear
Todd Presswood, CMEPP	La-Toya Salmon, Abbott
Kristen Killheffer, Siemens Healthineers	Samatha Gaddam, Alcon
Ugbaad Elmi, GE Healthcare	Daniel Lee, Baxter
Benoît Hébert, Teracero	Sarah Kalantari, Cdn. Hospital Specialties
Archie Shenoy, Abbott	Nilanka Liyanage, Siemens Healthineers
Christine Chun, Alcon	Charles Tam, Edwards Lifesciences
Michelle Joseph, Biotronik	Dinar Suleman, LifeScan
Seema Vyas, Medtronic	Jingxuan Cui, Boston Scientific
John Baloy, Abbott	Camellia Nezhad, Cdn. Hospital Specialties
Maria Vergiris-Bujouves, 3M Canada	Diana Fuszara, Stryker
Linda Aoues, Medtronic	Stephanie Gallone, Baylis Medtech
Inga Brencis, Johnson & Johnson Medtech	Connie Wong, Intuitive Surgical
Mandy Go, Abbvie (Allergan)	Daniel Quelhas, Beckman Coulter
Diana Faddoul, Cdn. Hospital Specialties	Deborah Reimer, Stryker
Nomi Steen, W.L. Gore	Young Kim, Johnson & Johnson Medtech
Alan Rodrigues, Abbott	Bo Hollas, Microbix
Venice Tan, Philips Canada	Samantha Jabrabad, BD Canada
Adrienne Chu, Sebia	Anna Tarakanova, Canon Medical
Nicole Khanna, Stryker	Enoch Owusu, BD Canada
Scott Crawley, MacuMira	Kelly Makimoto, SciCan
Karina Torres, Draeger	Wendy Holden, Baxter
Tom Lin, Quidel	Karl Luke, Quidel

Paminder Khurmi, Intuitive Surgical	Abby Chimonides, Boston Scientific
Lynn-Marie Green, Vernacare	Mark Arnold, Steris
Sabrina Telemaque, Siemens Healthineers	Kenneth Luk, Olympus
Sandra Leffler, Consultant	Raj Malik, Medtech Canada
Mia Spiegelman, Medtech Canada	Debbie Gates, Medtech Canada

Committee Meeting Welcome

Greg Leblanc opened the meeting and read Medtech Canada's Competition Law Compliance Policy: *The members of the Regulatory Committee are to provide direction to Medtech Canada on establishing a regulatory environment that supports timely adoption of new medical technologies in a fair and equitable manner. However, the Committee will at no time engage in discussion or activities that might serve to lessen competition among its industry members, such as price adjustments, customer segmentation, or the sharing of confidential, proprietary information.*

1.0 MEDEC RASC Meeting Minutes – Action Item Review

The minutes from the MEDEC Regulatory Affairs Committee meeting of September 26, 2022 were reviewed and approved.

Action Item Summary from September meeting:

1. Members are asked to continue to share examples of performance issues as they occur with Charles Tam, Charles_tam@edwards.com or Mia Spiegelman, mspiegelman@medtechcanada.org. Please continue to share examples.
2. Medtech Canada is seeking a contact in the Ministry of Environment to discuss Right to Repair. If you know of someone, please advise Raj Malik, rmalik@medtechcanada.org. UPDATE: No longer required.
3. Right to Repair position paper will be shared with the Regulatory Affairs Committee. Examples of the impact of technical protection measures being hacked and the potential risk if non-OEM service techs work on medical technologies are needed. If including a picture as an example, please provide a few bullets about what the picture is demonstrating. UPDATE: Mia will update later in the meeting.
4. Members are reminded to continue to send examples of classifications that don't align between EU and Canada and where there could be an issue with summary reporting. Please send to Debbie and Mia so sub-committee can share with Health Canada. UPDATE: Please continue to send examples.
5. Janice Wright will share information on the GUI-0054 recall document that was pulled from the Health Canada website with Mia Spiegelman. UPDATE: Janice shared this information.
6. Medtech Canada will confirm the date of the November bilateral meeting with Health Canada. UPDATE: Meeting was held on November 10.
7. AIS documents for the bilateral meeting will be due by October 7.
8. The link to the recording for the Bill 96 Quebec Language Law webinar will be shared with the full Regulatory Affairs Committee. UPDATE: the link was sent Sept 27.

2.0 Updates from Regulatory Affairs Sub-Committees and Task Forces

2.1 Steering Committee
The Steering Committee met to debrief the November 10 bilateral meeting. Updates will be shared either in the sub-committee updates or during the agenda item to debrief the bilateral meeting.

2.2 Diagnostic Imaging
The sub-committee met recently to discuss its scope and explore proactive advocacy of regulation development under Health Canada's Clinical Trials Modernization initiative as it relates to non-significant risk framework.

2.3 Digital Health
Ugbaad Elmi indicated that there is no update since the last meeting. A meeting of the sub-committee has been scheduled for January 11, 2023. As LifeScan has decided not to renew its membership, Dinar Suleman will be leaving the sub-committee. The sub-committee will be seeking a new co-chair.

2.4 Education/Training
The 2022 Regulatory Conference held in June and November included four days of live sessions, 5 breakout sessions, and 319 attendees.

Health Canada has noted that they would like to explore hybrid options for bilateral meetings.

Questions from the conference that weren't answered have been shared with Health Canada and others.

ACTION: Medtech Canada will follow-up with Health Canada regarding the unanswered questions from the conference.

It was suggested that Medtech Canada consider doing a survey to see what the preference of attendees would be for future meetings – hybrid, in-person, or virtual only.

2.5 Global Regulatory Affairs
IMDRF Personalized Devices working group has two documents – need to determine if Medtech Canada will comment. IMDRF Chair is rotating to the EU next year and work is underway regarding meetings for next year. The March meeting will be in Brussels the week of March 13.

GHWP meeting will take place in February in Saudia Arabia. Agenda is still in development. U.S. FDA has joined GHWP. Japan is to be confirmed at the February meeting.

Health Canada and FDA are taking the lead on establishing pilots for single review. Other regulators have expressed interest but want to see what develops as Health Canada and FDA work through their pilots.

2.6 InVitro Diagnostic Devices
This sub-committee hasn't met in some time. Discussed with the sub-committee the possibility of joining the Laboratory/Medicine sector committee. The sub-committee met with the Laboratory/Medicine committee but a debrief hasn't taken place since that meeting.

2.7 Post-Market Vigilance

Clarity is being sought from Health Canada regarding the MDEL request to list suppliers and manufacturers in Section 5. At the November bilateral meeting, Health Canada confirmed that they will be sending an Excel document with what is currently on file.

The sub-committee is still seeking examples of summary reporting concerns/issues.

2.8 Pre-Market Licensing

Health Canada deficiency tool: the Bureau of Licencing Services is analyzing results/comments provided. The Bureau will continue to use the tool. There is a potential for the tool to be used for other application types in the future.

REP is still in the pilot phase, but it is expected to move into the voluntary phase once changes from the pilot have been made. The mandatory phase will be evaluated based on feedback during the voluntary phase. A joint pilot with the U.S. FDA for eSTAR will be launching in December 2022. Health Canada is likely keeping REP while testing eSTAR.

Health Canada accepts submissions in both the old format and in the ToC format. Industry has indicated that their preference is single review rather than the e-submission pathway.

ACTION: The RAC Pre-Market sub-committee will seek clarification from Health Canada on the format for submissions.

The sub-committee continues to monitor the situation regarding Public Release of Clinical Information (PRCI). Delays are being experienced with Health Canada taking more than 120 days for both review and posting to the website. Experience to date has shown that Health Canada is being lenient on timelines as everyone gets to understand the process. Administration of program is still a concern.

Medtech Canada has developed a Pre-Market Concerns Survey which provides an opportunity for companies to provide examples on issues with the Health Canada application process. The survey will include the Health Canada Deficiency Tool questions so that issues can be captured. Link to survey shared in chat, Pre-Market Concerns Survey (office.com), please use this form to share concerns.

There is no new information about updating the Regulatory Contact information. Members are encouraged to monitor the regulatory contact during the MDEL renewal process. Members are also encouraged to reach out to Health Canada to remind of any changes.

ACTION: The RAC Pre-Market sub-committee will follow-up with Colin / Health Canada re status of the Regulatory Contact pilot program.

2.9 Regulatory Cooperation Council

The sub-committee met recently and reviewed their scope. There are no updates from the Treasury Board re items submitted. Stakeholder meetings are communicated to Kelly Makimoto, but there hasn't been a meeting since 2020.

2.10 Medical Device Programme Performance / Cost Recovery

MDD's performance is positive with the majority of performance measures being within timelines. Fees for 2023-24 were shared in a report from Health Canada. April is the timing of the CPI increase that is used by Health Canada.

CRI-PERF sub-committee scope: "Medtech Canada's Regulatory Affairs Cost-Recovery and performance sub-committee collaborates with health Canada through an open, transparent, and continuous exchange of key performance indicators, economic indicators, and stakeholder feedback on the topics of Health Canada's performance trending, regulatory predictability, cost and process efficiency across the Canadian medical technology regulatory environment. These exchanges represent the ongoing shared commitments towards cost-effective and timely regulatory review performance towards maintaining the safe and effective, globally competitive, and innovative medical technology industry in Canada."

Important to still hold Health Canada to target timelines, even those that are not cost recovered. If have any feedback/concerns/questions please feel free to reach out to Charles Tam or Mia Spiegelman.

3.0 Medtech Canada / MDD Meeting 2022

Most of the items discussed at the November bilateral meeting have been covered under the sub-committee reports. Health Canada has indicated they would like to hold a hybrid version of the next bilateral meeting.

A request was made to share the agenda and AIS documents from the bilateral meeting with members. The recent Record of Decisions (RoD) included the AIS documents and it was suggested it might be best to only share the RoD. The membership requested that all documents be shared with RAC members.

4.0 New Business

Bill C-244: Copyright Act is at consideration in committee in the House of Commons. Medtech Canada has presented to the Committee and met with several MPs. Medtech Canada is finalizing its submission to the committee. Medtech Canada will have another opportunity to present its case to the Senate when this Bill moves to the Senate.

Bill S-5: This Bill started in the Senate and is now in the House of Commons. Medtech Canada has sent a submission to the house committee. At this time there is no intent to include medical devices. Health Canada will advise Medtech Canada when medical devices may be included.

Quality Assurance Committee: There was a strong response from Medtech Canada members to establish a Quality Assurance Committee. The first meeting of the committee will take place on December 14. Validation, risk assessment, summary reporting are some of the areas that might be discussed by the Quality Assurance Committee.

MDEL Licencing & International Suppliers: Medtech Canada has reached out to Health Canada regarding the missing "unlicensed" in the regulations which is creating confusion regarding the need for an MDEL by suppliers. If a supplier doesn't have an MDEL, then they can't import.

Seema Vyas, Joe DeCroos, Michelle Joseph, Linda Aoues, Debbie Spence, Mark Arnold, and Marisa Petrielli indicated they were interested in this issue and willing to help draft a response to Health Canada.

ACTION: Medtech Canada will send a request to identify those interested in attending a meeting with Health Canada.

Medical Device Shortages: The plan is to have the meetings on a monthly basis. Agenda items will be sought from all participants. Meetings with Medtech Canada participants will be held prior to and after the Health Canada meetings. Participants in the meeting include regulatory, supply chain, government relations, etc.

ACTION: If members are interested in participating in the Medical Device Shortages meetings, please send an email to Debbie Gates or Raj Malik.

Reporting on supply chain can be burdensome for Regulatory Affairs personnel. Important to include a regulatory perspective in discussions.

Other Business: Health Canada no longer providing License Intended Use information. This information is not being posted on MDEL. Suggested can look at RDS or through Access to Information request. RDS updates are still in process.

Health Canada has advised that guidance documents won't be published as PDFs in future as making more user friendly to meet accessibility issues. This should be discussed at the spring bilateral meeting.

Confirm Next Meeting Dates and Close

DATES for RAC Meetings 2023 – 9:00 am to 12:00 pm

- March 7, 2023
- June 6, 2023
- September 12, 2023
- December 5, 2023

Prior to the pandemic, meetings were held in person for about 30 people and others could join via teleconference. All meetings will have an online component. If any members are interested in hosting a RAC meeting, please reach out to Debbie Gates / Mia Spiegelman / Greg Leblanc.

Innomar has a conference room that could accommodate about 60 people.

ACTION: Shirley Furesz will investigate the space in Oakville to determine if it could be used for a Regulatory Affairs meetings.

Suggestion made to record the meeting. Minutes are taken for meetings. Believe recording the meeting would result in less openness in the discussion.

The meeting adjourned at 12:30 pm.

Action Item Summary:

1. Medtech Canada will follow-up with Health Canada regarding the unanswered questions from the conference.

2. The RAC Pre-Market sub-committee will seek clarification from Health Canada on the format for submissions.
3. The RAC Pre-Market sub-committee will follow-up with Colin / Health Canada re status of the Regulatory Contact pilot program.
4. Medtech Canada will send a request to identify those interested in attending a meeting with Health Canada regarding MDEL Licensing & International Suppliers. UPDATE: Request has been sent and first meeting is January 5, 2023.
5. If members are interested in participating in the Medical Device Shortages meetings, please send an email to Debbie Gates, dgates@medtechcanada.org, or Raj Malik, rmalik@medtechcanada.org.
6. Shirley Furesz will investigate the Innomar meeting space in Oakville to determine if it could be used for a Regulatory Affairs meetings.