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Meeting Minutes

Meeting Title:	RAC Pre-Market Licencing Sub-Committee	**Date:**	November 24, 2022
Place:	Microsoft Teams	**Time:**	11:00 am – 12:00 pm
Purpose:	Regular Meeting		

Present

La-Toya Salmon, Co-Chair	Abbott
Catherine Matthews, Co-Chair	Edwards Lifesciences
Aniline Soco	Abbott
Linda Guo	ICON
Michelle Joseph	Biotronik
Scott Crawley	MacuMira
Jessica Danti	Canon Medical
Venice Tan	Philips Healthcare
Anna Tarakanova	Canon medical
Dinar Suleman	LifeScan
Sara Lam	BD Canada
Susan Hou	Medtronic
Mary Semplicio	Advanced Sterilization Products
Caroline Sepiol	GE Healthcare
Linda Tremblay	Johnson & Johnson Medtech
Chun Kwan	Zimmer Biomet
Greg Leblanc	Cook Medical
Nomi Steen	W.L. Gore
Rebecca Cameron	Stryker
Young Kim	Johnson & Johnson Medtech (left at 11:40 am)
Charles Tam	Edwards Lifesciences
Dale Morgan	Myant (left at 11:40 am)
Danna Zylka	Insulet
Kenneth Luk	Olympus
Stefan Feix	GE Healthcare
Wendy Holden	Baxter
Mia Spiegelman	Medtech Canada
Debbie Gates	Medtech Canada

Committee Meeting Welcome

Cathy Matthews welcomed the committee members and read the competition policy statement: *"Medtech Canada members are encouraged to raise issues that have broad industry implications and are aimed at establishing a business environment that supports the medical device industry. However, participants 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."

Sub-Committee Scope

The scope of the Regulatory Affairs Premarket Sub-committee is to focus on matters that relate to all premarket (before approval to market is granted by Health Canada) regulatory matters. The subcommittee tackles pre-market licencing concerns and topics regarding new and existing regulations and guidelines. Where certain items require more focused concern, the subcommittee may create a separate task force or engage other subcommittee support. The Premarket subcommittee collaborates with Health Canada on matters of pre-market and fosters a vibrant, inclusive and collaborative work among its members.

Review Agenda

Cathy Matthews reviewed the agenda for the meeting.

Ongoing Medtech Canada Pre-Market Concerns Survey

Mia Spiegelman provided insight on the tool. Medtech Canada is asking members to provide feedback on applications where there are issues, whether resolved or not, so feedback can be provided to Health Canada. If you have a challenge that isn't reflected in the survey, please advise Mia and she will add it to the survey.

Mia showed the current analytics available through the survey tool. The feedback via the survey will be reviewed during all Pre-Market Licencing sub-committee meetings.

Medtech Canada encourages all members to use this tool. It was recommended that a reminder be sent to members to complete the survey tool prior to each meeting.

Additional questions will be added to the survey tool that are part of the Health Canada Deficiency Tool survey.

Health Canada Bilateral Updates

Deficiency Tool: Cathy Matthews shared the survey results with Ellie at Health Canada. Ellie is in the process of analyzing the information. The tool is being used for all new and amendment information and has become the status quo for Health Canada. The sub-committee will continue to monitor. Please bring any concerns/issues forward for sharing with Health Canada.

eSTAR/REP: Learned at the conference that REP is here to stay. Health Canada is looking to eventually move from voluntary to mandatory. ToC is coming and many companies are now using. If not currently using ToC, it is recommended it be used for a Class II product to get experience with the tool.

Members are encouraged to go to Health Canada's website to download the most recent application form before starting an application as Health Canada continues to make tweaks to the form.

REP Submissions: The device listings table (found in the print and fill application forms) have been replaced with a separate device details spreadsheet. Health Canada felt that the old table did not effectively capture the nuances of the licence structure types or regulatory activity being performed. The

goal of the device details spreadsheet is to minimize frequently encountered errors and provide guidance where possible.

Health Canada is aiming to launch a joint pilot for eSTAR with the U.S. FDA. For the joint pilot companies will need to have a CDRH account. Two separate submissions that go into the joint portal. MDD will be launching a Health Canada only pilot as well. Suggested reaching out to Health Canada to raise concerns again and seek insight.

ACTION: Review previous ask re more information and re-send to Health Canada to highlight concerns and provide feedback on desires of industry. Suggest that a similar document to the FDA guidance for eSTAR is needed.

FDA Guidance document, Electronic Submission Template for Medical Device 510(k) Submissions | FDA

Link provided by Cathy, Send and Track Medical Device Premarket Submissions Online: CDRH Portal | FDA

Guidance Documents:
Guidance Clinical Evidence Requirements for Medical Devices: Overview (including examples of clinical evidence requirements for medical devices) was posted November 15. A link was shared with RAC.

Guidance re Non-Significant change hasn't been released as yet.

If aware of a guidance document that isn't posted in the correct place or doesn't have a date, please let Mia know and she will share with Health Canada. Keep checking the website for announcements / postings.

Health Canada's Public Release of Clinical Information

This will be a standing agenda item. PRCI has been a requirement for class IV new and amended applications for eight months. In four months, March 2023, PRCI will be applicable to Class III new and amendment applications. Looking for feedback on issues/concerns. Feedback from industry has been the lack of redactions permitted.

Members also noted a delay in feedback from Health Canada, PRCI process taking longer than 120 days. Medtech Canada will continue to monitor.

Members should ask Health Canada to advise when something is out of PRCI scope.

Other Business

Greg Leblanc will share the free look-up for GMDN codes with Cathy Matthews.

IO to MDSAP webinar expected to be in early February 2023. SaMD webinar on December 15.

Confirm Next Meeting Dates and Close

Suggested that this sub-committee meet on a quarterly basis. La-Toya and Cathy will propose dates for quarterly meetings.

The meeting adjourned at 12:00 pm.