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Meeting Minutes

Meeting Title:	RAC Post-Market Vigilance Sub-Committee	**Date:**	April 22, 2022
Place:	Microsoft Teams	**Time:**	1:00 to 2:00 pm
Purpose:	Continue discussions on Summary Reports		

Present

Vivek Patel, Co-Chair	Zimmer Biomet
Inga Brencis, Co-Chair	Johnson & Johnson Medtech
Deborah Reimer	Stryker
Archie Shenoy	Abbott
Masha Bosse	Coloplast
Aniline Soco	Abbott
Dinar Suleman	LifeScan
Samantha Jafrabad	BD Canada
Nicole Khanna	Stryker
Katarina Jugovic	Stryker
Michelle Joseph	Biotronik
Danna Zylka	Insulet
Jessica Danti	Canon Medical
Mary Semplicio	Advanced Sterilization Products
Eliana Pouchard	Johnson & Johnson Medtech
Donna Krizman	Edwards LifeSciences
Marion Mints	Siemens Healthineers
Anna Tarakanova	Canon Medical
Charles Tam	Edwards LifeSciences
Diana Johnson	Medtech Canada

Committee Meeting Welcome

Diana Johnson welcome the committee members and read the competition 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."*

Summary Reporting

- Purpose of the meeting was to regroup with team on next steps
- We want to respond back to Health Canada with the challenges that we have

- From our last discussion in March 2022
    - To get feedback on scope of the challenges for classification differences between Canada and EU
    - As an industry there are multiple cases where we will not be able to leverage PSURs
    - Ex. Class I in EU but Class II in Canada – require biennial report but since in EU it's a class I device there will be no PSUR available - ECG cables, blood pressure cuffs, thermometers/thermometer probes
    - Ex. Class IIa device in EU but Class III in Canada – require annual report in Canada but since only Class IIa in EU, we would only get PSUR biennially – ultrasounds

- What is our ask from an industry perspective? (Discussion & Additional Points)
    - Would it be possible to leverage the PSURs that are biennial with a justification, even though they are required annually?
    - What is realistic from a Health Canada perspective? Option of buying time vs. exemption vs enforcement discretion
    - The impact of summary reporting is to all manufacturers, but the degree of impact is different based on size of company, number of devices etc.
    - On the drug side – Self Care Framework where there could potentially be exemptions for low-risk drugs. Ex. Contact lens & disinfectants
    - There are devices that are sold in Canada and not in EU, for which we would also need PSURs – most impact to devices sold in US & Canada
    - Combination of Marketing History & PSUR – Would Health Canada accept a PSUR one year and then the next year, it would be limited review of Marketing History and complaints to see if a trend is going up? Manufacturers would have to put a rationale if there are any issues.
    - When summary report was first introduced, some companies already had a process they could use vs. some companies had to create one but they are still in the process
    - In terms of products that will never have a PSUR – Would Health Canada accept a smaller review – trend analysis? Would other data be required?
    - If Health Canada will not give us a concrete idea on what is acceptable during this transition, it could become a company-by-company approach. We would have to explain how we are handling the transition and as a company we are maintaining compliance
    - Health Canada is open to discussion but as an industry we will have to comply with what is in the regulations
        - Metaphorically, if you have all the data in different systems/documents, you could staple all that together, put a cover on it on with device & date range covered and potentially satisfy the regulations
    - We need to figure out what the "Special Case" buckets are to close the gap
    - Our biggest risk is Time – could a potential position be made for this? (see point 4 below)
    - Another potential issue in terms of EU guidance not being finalized. The whole transition is delayed which is posing an issue. Ex. IVDD.

- Potential positions to Health Canada
    1. EU MDR – The implementation timeline of EU MDR has changed. Could we get enforcement discretion during this period? Specifically for manufacturers, summary reporting will come up during MDSAP audits starting Dec 23, 2022.

2. Time – Could our ask be around asking for flexibility on time to harmonize? As an industry we want to harmonize as much as possible, but it will take more time. When auditors start reviewing this year, they can look at our processes and procedures that we have available to create these reports but not necessarily be able to see one completed.

- Next Steps
    - Please pass on any examples of the following 3 buckets to the post-market committee.
        - Class II in Canada vs. Class I in EU
        - Class III in Canada vs. Class IIa in EU
        - Devices that require a summary report but no PSUR available (i.e., not sold in EU)
    - The goal is to create a position for Health Canada by the June Medtech conference.
    - Post-market team will compile & then review will be done by industry

- Additional Questions during meeting
    - Do we still need clarification on what is required for summary reports based on regulation vs. what is in guidance? Will an MDSAP auditor give us a finding on what should be provided vs. what MUST be provided?
    - In November 2021, Health Canada mentioned that the guidance document for summary report will be updated based on feedback from industry in winter. Can industry get a timeline when the updated guidance will be available? – This question will be posed at the bilat.

Confirm Next Meeting Dates and Close

The meeting adjourned at 2:00 pm.