Canada's Drug and Health Technology Agency

PMDE Industry Task Force (ITF) Meeting

Meeting Summary and Action Items

September 26, 2023, 2pm - 4pm EDT

Facilitator

Don Husereau

Industry Representatives

Jason Lee, *Head of Market Access and Stakeholder Relations, Amylyx*

Jefferson Tea*, Vice-President Medical & Scientific Affairs, Takeda*

Jennifer Glass, *RWE Lead Canada, Eli Lilly*

Jennifer Wu, *Health Data Strategy Lead, Roche*

Kevin Pollock*, Director of Real-World Evidence, International Markets, Bristol Myers Squibb*

Maria Luckevich, *Health Economics Associate Director, Novo Nordisk*

Nikolas Goyert-Stephens*, Senior Manager, Market Access, Biogen*

Subra Seshadri, *Manager Access for Anti-Virals and Hospital Business, Pfizer*

Virginie Giroux*, Director, Health Economic and Outcomes Research, Merck*

Véronique Gaudet*, Field Medical Advisor, Bausch Health*

Health Canada

Kelly Robinson, *Director General, MHPD*

CADTH staff

Heather Logan, *VP, Strategic Relationships and Initiatives*

Tarry Ahuja*, Director, PMDE*

Nadine Sulatycky*, Program Lead, PMDE*

David Stock*, Scientific Advisor, PMDE*

Farah Husein, *Director, RWE*

Peter Dyrda, *Director, Pharmaceutical Policy and HTA*

Brendan McIntosh, *Drug Program Advisor*

Regrets

Jefferson Tea*, Vice-President Medical & Scientific Affairs, Takeda*

Trish Caetano*, Director, Drug Data Services and Analytics*

ITF Meeting Discussion and Action Items

1. Welcome & Introductions

The Vice President of Strategic Relationships and Initiatives convened the meeting and welcomed everyone.

2. Objectives and Mandate

The PMDE Program Director provided an overview of PMDE and CoLab's structure, purpose and objectives.

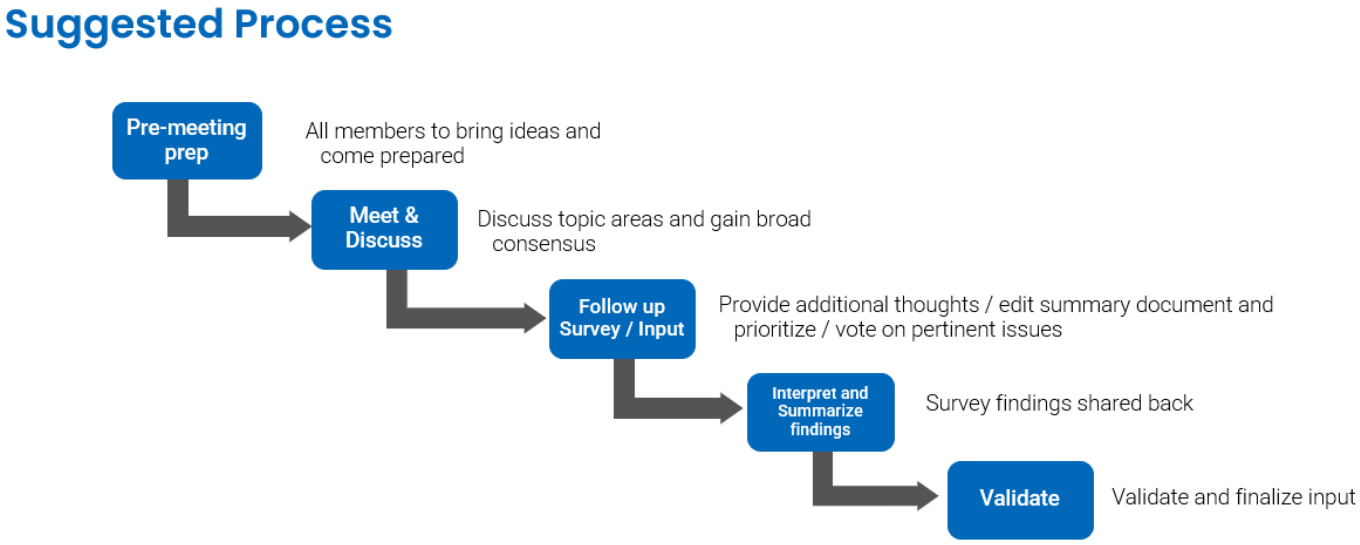
The Facilitator outlined the mandate and objectives of the Industry Task Force (ITF), highlighting that the work of the ITF will inform the PMDE query process, and the broader discussion around use of real-world evidence for purposes of decision-making. The ITF will identify opportunities and barriers in a Summary Document, including options on how to move forward on using industry-sponsored Real-World Data towards PMDE queries.

The ITF will report to the PMDE Advisory Committee, and ultimately CADTH's executive. The recommendations and Summary Document crafted by the ITF will be overseen by the PMDE Advisory Committee.

As part of the governance structure of the ITF, the members identified co-leads, Virginie Giroux will be the lead for industry and Tarry Ahuja will be the lead for CADTH. Leads will be responsible for providing input on agendas, gathering feedback outside of meetings, and reviewing the Summary Document.

3. Proposed Approach

The following approach was proposed by CADTH:



The ITF had limited feedback and agreed to this approach.

As part of the approach, offline surveys will be conducted in between meetings to capture additional thoughts and feedback, and findings will be amalgamated and then presented at the subsequent meeting.

4. Proposed Topic Areas

ITF members were presented with 6 proposed topic areas:

1. Types of accessible data
2. Operational requirements
3. Transparency
4. Integration into the PMDE process
5. Privacy and intellectual property
6. Collaborative data generation for decision-making

Members requested examples and further explanation of decision-making outcomes stemming from PMDE work. In general, PMDE queries include studies on utilization, safety, effectiveness, cost-effectiveness.

Members agreed that operational requirements should be addressed at a later meeting as they will depend on other topics.

There was discussion around societal impact and inequity and whether this feeds into the decision-making process at CADTH. While CADTH has taken steps towards its commitment to fostering health systems that reflect the diverse people of Canada, there is much work to be done in this area. CADTH has hired dedicated staff to advance these important issues.

The Facilitator indicated that if more time is needed to address some of the topics, additional meetings could be scheduled. There was also a recognition that this may be an iterative process, where elements from past discussions may need to be revisited in light of other points discussed in different topic areas.

Some topic areas appear to be linked (e.g., privacy, integration, operation) and there was general consensus these might be best discussed at the face-to-face meeting.

Action: CADTH PMDE staff to bring forward examples to next meeting.

5. Topic 1 – Types of Accessible Data

The ITF discussed patient supported programs (PSP) data, noting that data accessibility will differ from manufacturer to manufacturer, and across diseases. This variability across manufacturers is largely due to different internal standard operating procedures (SOPs) and compliance rules. The variability across diseases is mostly due different types of patient support programs being set up (e.g., "bridging" towards reimbursement). Depending on the use of data, there may also be privacy issues or issues accessing global data. Drug manufacturers may not openly share raw utilization data if drugs are being used off-label. Data in the public domain will be easiest to share.

Often times the data is not collected with the aim of answering specific health policy questions which may impact the relevance and utility. It would be beneficial to engage manufacturers as early as possible to design studies with these outcomes in mind. CADTH is not particularly interested in raw data but more so in aggregate level data, and data summary tables. Industry members indicated that raw data would be more difficult to share.

There was also discussion on manufacturers providing real world evidence (RWE) studies, market research in absence of data, and CADTH indicated that depending on the evidence and the questions being

answered, it may be of interest. CADTH also stated that appropriate reporting requirements would have to be met in order for studies or market research to be considered under the right circumstances.

The ITF also discussed at a high level the timelines for queries (which can take between 3 and 18 months depending on complexity, availability of data and study type), and how this will impact which data can be leveraged as the queries with urgent timelines cannot be delayed.

Participants also noted that manufacturers may be able to point PMDE to additional data outside of their own industry-sponsored data and how to overcome barriers to accessing these data. Some drug manufacturers may be incentivized and willing to partner with data registries for health technology assessment purposes.

Action item: industry members to investigate potential data sources that would be useful for PMDE.

6. Closing Remarks

Members were asked for their feedback about the meeting. A suggestion was made to have pre-read materials on PMDE process and potential project outcomes.

Action item: PMDE staff to share requested materials in advance of meeting 2.
Action Item: Members are to fill out Meeting 1 Survey ahead of meeting 2.

Adjournment

Meeting was adjourned at 4:00pm EDT. Next meeting will be October 24th, 2-4pm EDT.