Canada's Drug and Health Technology Agency

PMDE Industry Task Force (ITF) Meeting

Meeting Summary and Action Items

October 24, 2023, 2pm - 4pm EDT

Facilitator

Don Husereau, *University of Ottawa*

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*

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

Health Canada

Kelly Robinson, *Director General, MHPD*

CADTH staff

Tarry Ahuja*, Director, PMDE*

David Stock*, Scientific Advisor, PMDE*

Karleen Girn*, Program Development Officer, PMDE*

Farah Husein, *Director, RWE*

Brendan McIntosh, *Drug Program Advisor*

Regrets

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

Heather Logan, *VP, Strategic Relationships, and Initiatives*

Peter Dyrda, *Director, Pharmaceutical Policy and HTA*

Nadine Sulatycky*, Program Lead, PMDE*

1. Welcome & Introductions

The Facilitator convened the meeting and welcomed everyone. The Facilitator outlined the meeting agenda, and the meeting schedule.

2. Topic 1 – Types of Accessible Data

Meeting 1 Summary

The Facilitator reviewed the summary highlights from the first ITF meeting. Members agreed that level of detail provided in the summary was sufficient, and further detail will be considered for subsequent summaries. It was reiterated that PMDE is interested in aggregate level patient data, rather than raw patient data.

It was clarified that if drug manufacturers were engaged earlier by CADTH, e.g., at the early scientific advice stage, then CADTH could provide input on study designs to capture desired outcomes to answer post-market related questions. CADTH and its customers (payers and regulators) are willing to look at evidence outside of clinical trials, such as observational studies and utilization data in the appropriate context and setting.

PMDE query timelines could vary depending on needed approach from 3 months, such as a utilization study, to over 12 months, for an observational study or a systematic review of scientific literature. Timelines are driven by the customer's needs, for example if a requestor requires a more urgent timeline (e.g., 3 months), or where the query requestor may have a less urgent timeline (e.g., 6 to 9 months). There was a question raised around the manufacturer's ability to influence timelines at the early engagement stage. For reactive queries, coming from customers, the timelines are typically firm, however, CADTH can offer additional evidence products outside of their timelines if the customer sees value in these additional products. For proactive queries, CADTH typically has more time and could work with manufacturers to determine what data/evidence could be made available in a reasonable timeframe. All PMDE queries, whether proactive or reactive, are anchored to a policy decision and are valued by the query requestors. Customers tend to have less capacity to identify proactive queries as reactive queries are more urgent by nature, so they appreciate when PMDE suggests proactive queries.

In Canada, privacy issues will impact ability to access data both at the local and global level. There was discussion that patient support program (PSP) data could be a subgroup of information when forming the guidelines. Drug manufacturers usually own PSP data and have very specific governance procedures for this type of information. It may or may not be feasible to share this type of information, however PMDE is open to any piece of information which could be of value to answer queries. Accessing PSP may require additional discussion. CADTH will likely not require access to patient-level "raw" data from PSP databases, however these databases may be of value to inform or better frame policy questions or to validate or contextualize PMDE queries. There was suggestion to involve the manufacturer at the scoping phase of the query so that they can help identify potential data sources based on what the query requirements are and have the customer determine if the identified sources are of value. A challenge for this ITF will be to get unified guidance as each manufacturer will have different perspective and procedures, so a flexible approach will be needed.

Post-Meeting Survey Findings

The Facilitator provided a summary of the first ITF post-meeting survey findings.

- overall participants are supportive of the ITF process and topics.
- a variety of data sources were identified, and potential evidence sources.
- several limitations to accessing data were identified: study design, variability of data, internal processes, timeliness, permission, consent, confidentiality, legal/privacy.
- there is a lack of consistency amongst data sets and will largely depend on the therapeutic area being studied.
- early engagement and a collaborative approach will be the keys to successful use of data for PMDE.
- fit-for-purpose – the data requested should be dependent on the research question

The PMDE queries which are largely non-confidential can be shared publicly and with drug manufacturers, any confidential queries typically will become non-confidential after customers have had the opportunity to leverage query findings for decision-making. Non-confidential queries will be shared with the ITF as examples of questions jurisdictions are asking the PMDE program.

The PMDE process is distinct from CADTH's reimbursement review process where CADTH is scrutinizing a clinic data package to ultimately make a recommendation. The PMDE process is much more collaborative in establishing the policy and research questions and leverages CoLab to analyze the data to generate evidence reports for customers and no recommendations are made. The ITF will determine if manufacturer-sponsored data could be included in the data being analyzed by the CoLab network.

3. Topic 2 – Transparency

The Facilitator introduced the second topic area, transparency.

How do we establish transparency of what data exists and what is being shared?

Transparency has different meanings, and it is important to define this. There will be cases where the existence of information can be shared, however the information itself cannot be shared. It needs to be understood by the CADTH and its customers if there are boundaries on what can be shared, and why studies may be excluded.

Studies presented or published are in the public domain and it may not have been captured in a scientific literature review. It depends on the question being asked to then ascertain if there is information available. There is a need for details, as much as possible, regarding what is being asked for the PMDE queries. Some manufacturer conducted studies may be deemed unfeasible and are halted at the preliminary stages or sooner. CADTH indicated that even knowledge of this may be helpful as it may prevent unnecessary scoping or duplication.

Data transparency can depend on the privacy regulations as per the jurisdiction and the drug manufacturer. It may depend on how transparent CADTH intends to be with the data being shared. It is important to reiterate that the drug manufacturers may not be the data owners, therefore the information which can be shared is dependent on the contracts with the data owners. There may be constraints from the global level of the drug manufacturer, despite the local level requesting the information.

Are all available evidence, including protocols and analysis plans, being shared (both positive and negative)?

For network meta-analyses, the drug manufacturer may decide the study is not appropriate for aggregation for various reasons. However, CADTH may want to include this study in their appraisal. This misalignment is not intentional, and each perspective should be considered. By standard operating procedures (SOPs), researchers are committed to the research despite what the findings may be. Certain studies may not be published by drug manufacturers; however, it can be shared with CADTH through a confidentiality agreement. CADTH would be open to this possibility as the goal is to have access to information to help policy decision-makers answer the PMDE queries.

Feasibility analyses may be completed by drug manufacturers to assess if a clinical study should be conducted. If the feasibility analysis does not yield positive results, then the drug manufacturer may not wish to share this as a clinical study will not be conducted. The intent is not for CADTH to critique the work of drug manufacturers. However, if the drug manufacturer can share information of a certain clinical direction not being taken, then this would be useful for CADTH to know.

If a PMDE query is confidential, then there can be a conversation between the PMDE program and the query requestor to share that a drug manufacturer may have information which can be useful for answering the query. This conversation can lead to the possibility for the query requestor to share information about the query confidentially to the drug manufacturer. If data is shared by the manufacturer and there is a need to keep that confidential that is an option as it is beneficial to still have this evidence for decision making. The desire would be to receive more evidence that can be shared versus that which must remain confidential.

Transparency across reasons when data cannot be shared. This will provide additional context when this information is shared more broadly.

Ideally, it would be beneficial to give a rationale as to why a drug manufacturer cannot provide data. Some possible reasons may be the drug manufacturers are not the data owners, the permission is not granted from the global level, or the information is not yet published. Other possible reasons may be the difficulty of logistics such as gathering patient consent for PSP data or the drug manufacturer information not following the fit-for-purpose question posed by CADTH. Timelines are important to consider, as drug manufacturers may not be able to fulfill more urgent timelines to gather and share information. It would be shared with the query requestor that the drug manufacturer was contacted in all these cases. The manufacturers flagged that generally their preference would be to provide additional information or context as to why evidence could not be shared as a way to provide transparency and circumvent scrutiny.

Additionally, CADTH should provide context as to why a drug manufacturer was not contacted during the PMDE query process. The future goal is to normalize the process for flagging a query for the drug manufacturer in concern to their drug molecule. While broad details can be provided between the query requestor and the drug manufacturer, there would an expectation that individual names would not be cited in reports or conversations. There may be scenarios where drug manufacturers may be afforded the opportunity to share information confidentially to query requestors, however this information would need to remain confidential until a mutually agreed upon release. It will be noted for CADTH, and this information would not be included in published reports.

It would be important to note that drug manufacturers partner with patient registries and the registries are the data owners. Patient consent and data sharing are essential conversations to have with patient registries. CADTH is working to understand where data lies and to work with all data owners.

Acceptable level of transparency/detail in final PMDE report – will this impact the ability to share data?

Some PMDE queries are confidential until the final scientific report is published. This will also apply to the information drug manufacturers are able to share, either the information is shareable in a published report, or the information is confidential and will only be shared with the query requestor. The data would be fully visible to the policy decision-maker and the scientific report would be confidential until it is published. The goal is to prevent redaction of the data after the publication.

CADTH prefers to use as many clinical experts as possible in their process, and this aligns with the PMDE query process. If the drug manufacturer shares information provided by a clinical expert in the field, this will be highlighted in the scientific report. The main difference is the PMDE program does not provide recommendations, the program only provides policy implications and an implementation advice panel.

4. Closing Remarks

Members were asked for their feedback about the meeting. It was suggested to prepare for the November meeting topic areas: Privacy and IP, Integration into PMDE process, and Operational Requirements.

It was noted that all documents can be accessed by ITF members through SharePoint site, which needs to be logged into first before access being granted.

Action item: PMDE staff to share the Meeting 2 Summary and pre-meeting questions.
Action Item: Members are to fill out Meeting 2 Survey ahead of meeting 3.

Adjournment

Meeting was adjourned at 4:00pm EDT. Next meeting will be November 28th, 9 am - 4pm EDT in person in Ottawa at the CADTH headquarters.