Canada's Drug and Health Technology Agency

PMDE Industry Task Force (ITF) Meeting

Meeting Summary and Action Items

January 16, 2024, 2pm - 4pm EDT

Facilitator

Don Husereau

Industry Representatives

David Shum, *Director, Strategic Access & Pricing, Roche*

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

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

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

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

Tarry Ahuja*, Director, PMDE*

Nadine Sulatycky*, Program Lead, PMDE*

David Stock*, Scientific Advisor, PMDE*

Brendan McIntosh, *Drug Program Advisor*

Karleen Girn, *Program Development Officer, PMDE*

Regrets

Heather Logan, *VP, Strategic Relationships and Initiatives*

Farah Husein, *Director, RWE*

Peter Dyrda, *Director, Pharmaceutical Policy and HTA*

Jennifer Glass, *RWE Lead Canada, Eli Lilly*

1. Welcome

The Facilitator and PMDE Director convened the meeting, reminding members of the upcoming final ITF meeting, in-person, in March, and stated their appreciation to all the ITF members for being engaged in discussions thus far. The Facilitator outlined the meeting agenda, and the meeting schedule. The Facilitator explained that after this ITF meeting, the summary document will be drafted.

2. Summary of Topic Areas 3, 4, and 5

Overview of Summary Highlights

The ITF meeting 3 summary highlights were reviewed for topic areas 3 – operational requirements, 4 – integrating into the PMDE process, and 5 – privacy and intellectual property. Also, the ITF post-meeting 3 survey findings were collated and shared on SharePoint.

The summarized findings were presented:

Topic 3 - Operational Requirements

- In Canada, databases are mostly industry sponsored, governance and stewardship managed by the data holder and the manufacturer will have ownership or co-ownership of the protocol.
- Significant variability with the structure of the databases and shareability will largely depend on the agreement in place.
- Timeliness of accessibility will differ greatly; some data/evidence can be accessed in 1 to 2 weeks and rare disease data can take 1 to 2 years.
- Using existing CADTH platforms to share evidence seemed favourable and likely most efficient as they are vetted and have appropriate security in place.
- Legal agreements will need to be in place, ensuring confidentiality, intended use and publication requirements.

Topic 4 – Integrating into the PMDE Process

- Industry could be involved as early as the scoping and refining phase.
- Collaboration between manufacturers, facilitated by CADTH, to send joint feedback and avoid duplication of work.
- Engaging industry regarding post-market evidence needs at the pre-submission stage or early scientific advice would be ideal.
- Industry's financial investment in data structure is seen as a risk if it does not yield high-quality real-world data and will also depend on the impact and outcomes of the query.
- Manufacturers have the right to refuse to participate in CADTH projects for a multitude of reasons, however CADTH will share the refusal and the rationale of the refusal in its reports.
- Query timelines will be a barrier to industry participation.

Topic 5 – Privacy and Intellectual Property

- Patient consent and global approval will be challenging when it comes to sharing PSP data.
- For other data, intended use by PMDE must align with pre-specified terms in the original agreement.
- IP will be on a case-by-case basis. Where there is co-ownership, all parties will need to agree to sharing.
- Is answering policy and/or post-marketing queries considered research? The question is an important one for ensuring "consent for research" used by registries/databases/PSP still applies.
- If manufacturers were listed as authors in CADTH reports, they would have to review and approve the contents of the report.
- Peer-reviewed publications are of concern.

Post-Meeting Survey Findings

- Database structure is not uniform: data/evidence access will be on a case-by-case basis.
- Using existing CADTH platforms to share evidence seems favourable, however some legal hurdles will need to be addressed.
- Timelines for access to evidence range quite a bit, largely due to legal requirements.
- Industry would like to be involved throughout the query process as early as possible.
- Members unanimously agreed that CADTH post-market data needs can be considered during the industry evidence generation process.
- Permission to publish will be on a case-by-case basis; peer-reviewed journals are of concern to industry, however, use for decision-makers / HTA would be viewed more favourably.

3. Topic Area 6 – Collaborative Data Generation for post-market evaluation and decision-making

Overview of PMDE Query Process

The PMDE Program Lead reviewed the steps of the PMDE query process including: the query submission, scoping and refinement, query response team engagement and feasibility assessment, delivery of draft protocols and plans, evidence generation and analysis, knowledge dissemination, and follow-up for impact.

It was explained the PMDE customer could be federal (Health Canada, Public Health Agency of Canada), or the provincial, territorial, or federal drug plans, as well as PMPRB and pCPA. It was clarified that the PMDE Program Development Officers do a preliminary feasibility assessment once the query is received, and query alerts are sent to the CoLab research network to notify the research teams of the potential query and to receive their input. Data access is an important factor in assessing the feasibility of the query.

The purpose of PMDE queries is to focus on answering the health policy question and fulfilling the needs of decision-makers. It was clarified the work the PMDE program focuses on post-market effectiveness and safety of marketed drugs in Canada, however unlike the reimbursement review program, PMDE does not provide recommendations. In the chance of PMDE reports being used for reimbursement reviews, the drug manufacturer(s) would be notified.

There are several potential opportunities in the query process to engage stakeholders to receive feedback about the query including the design, protocol, and report. It was noted that the manufacturer(s) for the drug(s) being studied can be engaged directly rather than through the public engagement part of the process.

It was reiterated that the granted research teams have funds for the three years and their funding is based on their capacity, expertise, skillset, and data assets. The query response team can also include network collaborators or ad hoc collaborators who are researchers that would have contracts for query work. There was a question asked around the feedback process, particularly around protocol feedback, and whether PMDE would adjust based on the feedback, to which it was explained that if the feedback is deemed valid and feasible to address by internal CADTH experts and CoLab Researchers it would be addressed in the protocol for the respective query. Thus far, there has not been a request to re-evaluate the evidence from a PMDE project. If this occurs, then the appropriate internal CADTH experts would be engaged to determine a path forward.

It was discussed where potential industry engagement can occur in the future PMDE query process, for data access. In the query process, after preliminary scoping and refining and determining if the query is a

"good fit", industry could be engaged at the same stage as the query response team is engaged, where the feasibility assessment is conducted and discussions around the available data take place. Industry members ask if there could be engagement at an earlier stage in the PMDE query process; however, it was noted that the query may or may not move forward depending on feasibility or the needs of the decision-maker.

It was clarified that the CoLab research teams do the evidence generation and analysis, and there is a layered approach for the interpretation of the evidence and findings. Clinicians, content experts and PMDE staff are involved with the interpretation of the evidence to anchor the data back to answering the health policy question in a clinically meaningful way. The evidence and interpretation of the findings provided by the PMDE program are used by the customers to make policy decisions.

What would be the process and factors for consideration to collaboratively produce this RWD/E for post-market evaluation?

Members agreed that a proactive agreement would need to be in place between industry and PMDE to avoid time delays and address any barriers upfront so that work can commence as soon as possible. A standardized process and template legal agreement would streamline the process from a legal perspective.

Discussions regarding considerations for evidence generation could occur during engagement in the Early Scientific Advice Program and at the stage of writing recommendations reports in Reimbursement Reviews. The pre-submission meeting was also suggested but may not be as helpful to have discussions as it may be too early for producing post-market evidence. Discussions during a post-submission meeting would be beneficial to address feedback from the process and be proactive for future PMDE queries. It was suggested that an informal approach to discussing the evidence uncertainties for the considered drugs, rather than only during a reimbursement review would be helpful for manufacturers, however, may not be feasible for CADTH to do this for all submitted drugs. Currently, there is a case-by-case basis where evidence uncertainties are addressed during a reimbursement review.

Early understanding of the gaps in evidence would be the most beneficial from the industry's perspective; there may be a need for post-market data during drug pricing negotiations. CADTH's Drug Data and Analytics team is working on proactively identifying patient registries, particularly for rare diseases. The team is also helping patient registries become useful for pricing negotiations by positioning the registries to collect data prospectively.

Are there alternative pathways to generate this RWD/E?

It was highlighted that it depends on the needs of the query. When engaging industry, they likely have a good sense of the data landscape and can explain which pathways they are using to generate RWD/E. However, the pathways can evolve over time.

Is there a willingness to generate post-market data collaboratively?

Yes, there is a willingness to generate post-market data collaboratively.

It was asked if patient groups can submit a PMDE query. Currently, patient groups cannot submit a PMDE query. However, patient voices are valued and groups are engaged during a PMDE query process, in accordance with the PMDE engagement framework. In addition to ad hoc query engagement, two patient representatives sit on the PMDE Advisory Committee to provide their perspectives on the program.

What are some barriers or instances where this collaborative data generation will be challenging or unfeasible?
Due to time constraints, ITF members will provide their perspective through the post-meeting survey.

Are there opportunities to trial collaborative data generation of RWD/E?
Due to time constraints, ITF members will provide their perspective through the post-meeting survey.

4. Closing Remarks

Members were asked to come prepared for the March meeting to discuss the draft ITF Summary Report.

Any additional input can be sent to the Program Lead, all documents can be accessed by ITF members through SharePoint site, and the next meeting will be March 26, 2024, at the CADTH Ottawa office.

Action item: PMDE staff to share the Meeting 4 Summary and draft ITF Summary Report.
Action Item: Members are to fill out Meeting 4 Survey ahead of meeting 5.

Adjournment

The meeting was adjourned at 4:00pm EDT.