Canada's Drug Agency
L'Agence des médicaments du Canada

Report Brief

Industry Task Force Summary Report

Issue

One of the new work streams in the expanded mandate of Canada's Drug Agency involves increasing pan-Canadian data collection and expanding access to drug and treatment data, including all types of real-world evidence (RWE). Collaboration in this area is essential to reducing barriers to access and bridging evidence gaps across the life cycle of a product.

The pharmaceutical industry is increasingly collecting and sponsoring the generation of real-world data. This includes patient-level data collected outside of traditional clinical trials from a variety of sources (e.g., chart reviews, clinical registries, patient support programs). RWE is the clinical evidence that is derived from the analysis and synthesis of real-world data.

Health data are often collected, analyzed, and stored in different ways — with different ownership arrangements and needs for patient consent and privacy — which can create barriers to sharing. Despite this, manufacturers are interested in sharing aggregate data and evidence with health technology assessment bodies to expand the evidence that is available to inform policy decisions.

Background

We established a time-limited task force in September 2023 to formally explore sharing pharmaceutical industry–sponsored RWE with our Post-Market Drug Evaluation (PMDE) program. The PMDE program, which launched in 2022, offers an ideal platform to test approaches to using this type of evidence. It operates a network of experienced research partners to deliver evidence about drugs approved for use in Canada. The research teams are experts in applied research, scientific methods, and data analysis.

Approach

The task force, composed of representatives from industry, Canada's Drug Agency, and Health Canada, provided a forum for constructive dialogue about how to effectively operationalize access to and use of industry-sponsored RWE. This initiative presented an innovative approach to improving access to data in Canada and marked a first-of-its-kind collaboration. In the span of 4 meetings, the task force examined issues related to evidence-sharing, such as scope, ownership, transparency, operational requirements, privacy, process, and collaboration.

The summary report presents the findings from these meetings and is organized into 6 main themes:

- types of RWE that can be shared
- implications of ownership of RWE
- level of transparency (required and acceptable)
- operational requirements and conditions for effective sharing
- implications for the PMDE program at Canada's Drug Agency
- collaborative evidence generation for post-market evaluation and decision-making.

Findings

The report emphasizes early engagement between manufacturers and Canada's Drug Agency in the PMDE query process and more broadly within the drug life cycle across our organization. It recommends earlier engagement to gather a wider range of evidence, reduce delays in accessing evidence, and identify potential gaps in evidence during the drug review process to prepare for future post-market needs. The report also provides a rationale for, and suggests who should lead, proposed actions that can help facilitate the use of industry-sponsored RWE.

The summary report does not represent an approved plan, but it will inform the PMDE program and its Advisory Committee. Our aim is to incorporate some of the proposed actions into the current PMDE query process before the end of the fiscal year.

For more information on the PMDE program, visit the **program webpage**.

For the full Industry Task Force Summary Report, visit the **PMDE Industry Task Force webpage**.

Canada's Drug Agency
L'Agence des médicaments du Canada

Canada's Drug Agency is a pan-Canadian health organization created and funded by Canada's federal, provincial, and territorial governments. We're responsible for driving better coordination, alignment, and public value within Canada's drug and health technology landscape.

cda-amc.ca

August 2024