Laying the Foundation for a New Health Canada and HTA Alignment:

PERSPECTIVES ON EVIDENCE AND VALUE ASSESSMENTS FROM THE BMORS–PCODR PILOT PROJECT
Disclosures

- The presenters have no conflicts to disclose.
Overview

• Drug review process in Canada
• Why a pilot?
• Outcomes of the pilot
• What’s next?
Health Canada – BMORS Regulatory Activities

- Bureau of Metabolism Oncology and Reproductive Sciences
- Pre-submission meetings
- New Drug Submissions and Supplemental New Drug Submissions
  - 300 days target timeline, focus of review: safety, efficacy, quality
  - Priority reviews - 180 days target review time
  - Notice of Compliance with Conditions – 200 days target review time
Overview of Drug Review to Access in Canada

- Health Canada
- CADTH (CDR and pCODR)
- INESSS (Quebec)
- Pan Canadian Pharmaceutical Alliance (pCPA)
- F/P/T Ministries of Health and Provincial Cancer Agencies

Regulator (Effect & safety)

HTA (Assess value)

Price negotiator

Decision maker/funder
## Timely Access: How does Canada compare?

<table>
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<tr>
<th>Country</th>
<th>HTA agency</th>
<th>HTAs (n)</th>
<th>Time to HTA conclusion (# days)</th>
<th>Min (# days)</th>
<th>Max (# days)</th>
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<td>-296</td>
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<td>569</td>
<td>321</td>
<td>-296</td>
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</tr>
</tbody>
</table>

**Source:** Exploring the time delay between regulatory approval and health technology assessments (HTAs) of oncology therapies in France, Germany, England, Scotland, Canada, and Australia. Jaksa, A; JCO, 2017.
Timely Access: How does Canada compare?

Average Number of Days Between Regulatory Body Drug Approval and HTA Agency Reimbursement Decision

- pCODR/Health Canada: 213 days
- PBAC/TGA: 418 days
- SMC/EMA: 427 days
- NICE/EMA: 558 days

Source: Pharmaceutical Accelerated Access Schemes; Mackenzie Mills, ISPOR European Congress; Nov 8, 2017
Timely Access

- For pre-NOC submissions, the mean timeline is 135 calendar days from NOC issuance to Notification to Implement of pERC recommendation.
- How can we continue to improve the timeliness of access for patients?
  - Through collaboration, communication
  - Identifying efficiencies
Why a pilot?

- To strengthen *collaboration* between Health Canada and CADTH
- To explore opportunities to develop a more integrated model for drug review in Canada in the *future*
The scope of the pilot
What did we do?

- Open communication
- Joint teleconferences
- Shared documents
- Observing respective review meetings
- Discussion of review timelines
- Discussion of potential revisions to indications
What did that look like?

- 23 Industry meetings
- 13 HC-pCODR meetings
- 2 Learning sessions (BGTD, TPD, pCODR,)
- 6 Submission specific meetings
- 2 HC observed: pERC; check in meeting
- 4 pCODR observed: HC pre-sub meetings
- Outreach meetings with HC and industry partners
- ongoing dialogue
Timeline of the pilot

Early days of the pilot

- Summer 2016: Initial discussions and case studies
- October 2016: Proposed pilot project
- November 2016: Identified potential industry participants
- December 2016: Targeted letter sent to industry
- January 2017: 2 industry participants joined

Evolution of the pilot

- February-May 2017: Series of meetings with industry
- June 2017: 2 additional industry participants joined
- July-Sept 2017: Information sharing on active reviews
- Nov/Dec 2017: 1st aligned review completed
- Oct 2017-April 2018: Ongoing discussions to broaden alignment work
Evaluation of the pilot

- Informal interviews with industry partners
- Joint teleconference between Health Canada, CADTH, industry to discuss experience with the pilot
- Overall support for the pilot and to ongoing exploration to further identify *efficiencies*
- 5 key themes emerged from the evaluation…
Themes emerging from the evaluation

1. Timelines/access
Themes emerging from the evaluation

2. Duplication of work

**Dilbert**

I started a task force to eliminate redundancies in our internal processes.

Really? I'm doing the same thing.

By Scott Adams
Themes emerging from the evaluation

3. Distinct Mandates of Health Canada and CADTH
Themes emerging from the evaluation

4. Communications/Relationships
Themes emerging from the evaluation

5. Requirements of Regulatory vs HTA Reviews
What’s next?

• Expand the information sharing more broadly within Health Canada and CADTH
THANK YOU!