CADTH Drug Portfolio Information Session

Pharmaceutical Manufacturers, Industry Associations, and Consultants

OCTOBER 3, 2017
Welcome
Session Objectives

• CADTH is committed to ongoing, two-way communication with stakeholders
• Today is an opportunity to:
  o Share program updates from the CADTH Drug Portfolio
  o Provide updates on other CADTH initiatives
  o Answer questions and discuss key issues
Presenters

• Dr. Brian O’Rourke
  President and CEO

• Mr. Ken Bond
  Director, Patient Engagement, Ethics, and International Affairs

• Ms. Alexandra Chambers
  Director, CADTH pan-Canadian Oncology Drug Review

• Dr. Trevor Richter
  Director, CADTH Common Drug Review and Optimal Use
# Overview of the Agenda

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Questions

• Questions of clarification after each presenter
• Open Forum at the end of the session
• In-person:
  • Please use a microphone for the benefit of on-line participants
• On-line:
  • Email your questions to events@cadth.ca
International Trends in HTA
Orphan and Ultra-Orphan Drugs

- Orphan drugs set to be 21.4% of worldwide prescription sales by 2022*
- Determining conditions for unmet need or exceptional cases challenging

Oncology Drugs

- A growing demand leading to a growing pipeline
- Challenging evidence reviews because of trial designs and the demand for early access
- Pricing considered high
- Post-market studies including real world evidence becoming more important
CAR-T Immunotherapy

Chimeric Antigen Receptor T cells (CAR-T)
- Trials have shown high response rates but also severe adverse events
- Characterised in media as potential game-changers
- August 30, 2017, FDA granted regulatory approval to tisagenlecleucel
  - Approved for acute lymphoblastic leukemia in patients up to 25 yr (600 patients annually).
  - Response rates of 82.5% and 1-year survival of 80%.
- CADTH working group on gene therapies and regenerative medicines
Increased Regional and Global Collaboration
Stakeholder Involvement

- Increasing interest in models for stakeholder involvement: patients, caregivers, clinicians, broader public
- European Patients Forum (EPF) and EUPATI
- Patient-Focused Medicines Development
- Innovative Medicines Initiative (IMI)
- Patient Involvement in Health Technology Assessment. K Facey, H Pugh-Hanson, A Single, eds. Springer, 2017
HTA Alignment with Regulators

- **Europe’s Innovative Medicines Initiative (IMI)**
  - Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients.
  - Numerous projects underway such as ADAPT-SMART

- **EMA-EUnetHTA**
  - Joint scientific advice
  - From adaptive licensing to adaptive pathways (MAPPS)

- **Centre for Innovation in Regulatory Science**
  - HTA Steering Committee and research program

- **NEWDIGS – MIT**
  - Integrated Efficacy to Effectiveness (E2E) clinical trials
  - Innovative financing and reimbursement models
Payers Addressing Affordability

• Value frameworks
• Prioritization
• Innovative pricing models
• Joint price negotiation
• Risk sharing agreements
• Budget Impact Analysis
CADTH Health Technology Management Strategy
New Federal Funding for CADTH

- Health Technology Management Strategy that supports the overarching and shared priorities of the F/P/T ministries of health, among them:
  - Making decisions informed by evidence
  - Improving the affordability and accessibility of prescription drugs, and improving prescribing and appropriate use
  - Advancing pan-Canadian collaboration on health innovation, and specifically examining the role of technology management.
- Guided by the vision of creating more adaptable, innovative and affordable health care systems for all Canadians.
From HTA to HTM

• More focus on providing relevant and useful evidence to support decision-making at the policy level and at the patient-clinician interface.
• Not about discarding HTA principles and methods
  • HTM builds on the science of HTA with an increased focus on lifecycle management, stakeholder engagement, and implementation support.
• Not transformational change, but a natural progression from current CADTH activities.
HTM Strategy – Key Areas of Focus

1. Governance and Priority Setting
2. Assessment and Evaluation throughout the Technology Lifecycle
3. Strengthening the Evidence to Action Connection
4. Measuring Impact and Improving Value for Money
Governance and Priority Setting

• Enhance CADTH’s priority setting process: comprehensive, inclusive, transparent.
• Expand horizon scanning activities to enhance awareness of emerging technologies
• Expand the breadth and scope of evidence reviews
  • Explicit consideration to the unique needs of groups such as Indigenous peoples, mental health community, and Canadians living in rural, remote and northern areas
• Support to CADTH customers:
  • Options for a national formulary
  • Development of evidence-based procurement processes for non-drug technologies
Assessment Throughout the Technology Lifecycle

• Align reviews with Health Canada (drug and device)
• Create a distributed network of HTA producers
• Expand/evolve CADTH Scientific Advice program
• Contribute to the design of a framework for Real World Data use in Canada and conduct reassessments
• Grow existing programs and launch new initiatives
Strengthening the Evidence-to-Action Connection

- Provide enhanced implementation support
  - Greater uptake of evidence-informed practices
  - Increased resources at the local level
- Create a clearing house of decision aids and tools
- Enhance engagement with patients and providers
Measuring Impact and Improving Value for Money

- Develop collaborative approaches to indicator development, performance measurement, and quality improvement
- Enhance CADTH analytics capacity
  - Make more information available to a wider range of users
  - Provide customised reports to support policy-making and monitor implementation
Next Steps

- Details of the Strategy will be elucidated in a new Strategic Plan being developed by the CADTH Board of Directors
  - Implementation in April 2018
CADTH Drug Portfolio: Overview and Updates
CADTH Common Drug Review and Therapeutic Review Updates
Overview

- **CDR Updates**
  - New CDEC membership
  - CDEC meeting schedule
  - CDR statistics
  - Advance notification procedure
  - Planned updates to submissions guidelines
  - Collaborative space

- **Drug Portfolio Consultations**
  - Resubmission criteria
  - Submission and review process for biosimilars
  - New process for companion diagnostics

- **Therapeutic Review Updates**
  - Therapeutic review topics
  - Consultation on expanded therapeutic review process
CDEC Update

• Call for CDEC nominations was issued in 2017
• CADTH thanks all outgoing CDEC members:
  • Lindsay Nicolle (Chair), Frank Gavin, Irvin Mayers, and Harindra Wijeysundera

Current CDEC members:

James Silvius (Chair)  Allan Grill (new)
Silvia Alessi-Severini   Peter Jamieson
Ahmed Bayoumi            Anatoly Langer
Bruce Carleton          Allen Lefebvre
Alun Edwards (new)       Kerry Mansell
Bob Gagne (new)          Yvonne Shevchuck
Ran Goldman (new)       Adil Virani
CDEC Update

- CADTH will begin holding CDEC meetings in August and December on an annual basis
  - Increase from 10 to 12 CDEC meetings per year
  - Previously these meetings were scheduled only if necessary due to a high volume of submissions
Evolution of pre-NOC process for the CDR program:

2008      Pilot process for pre-NOC submissions
July 2009  Pre-NOC process for priority review of new drugs
Dec. 2009  Pre-NOC priority review of new drugs and drugs with new indications
Nov. 2012  Removal of priority review criteria
March 2014 Biosimilars eligible for pre-NOC
May 2014   All submissions eligible for pre-NOC
CDR Pre-NOC Submissions

- Initial Pre-NOC process (restricted to priority reviews): 12%
- Priority review criteria removed: 36%
- All restrictions removed: 38%
- Currently Over Half: 62%
- Currently Over Half: 58%

CDR Pre-NOC Submissions

- Proportion of pre-NOC submissions continues to increase
- CADTH would like to further reduce the interval between issuance of an NOC from Health Canada and issuance of a recommendation from CDEC or pERC

- Questions:
  - What factors influence a decision to file on a pre-NOC basis versus a post-NOC basis?
  - What are the important barriers to filing a pre-NOC submission?
CDR Advanced Notification

May 2014
- Voluntary notification (12 months)
- Mandatory notification (20 business days)

September 2016
- Mandatory notification (≥120 calendar days)

June 2017
- Expedited Health Canada reviews (≥30 business days)
- All other drugs (≥120 calendar days)
CDR Advanced Notification

Effective for January 2018
Minimum notification for all submissions and resubmission is ≥30 business days.

<table>
<thead>
<tr>
<th>Advance Notification Process</th>
<th>Days Prior to Filing Date</th>
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<tbody>
<tr>
<td>CADTH preferred advance notification</td>
<td>≥ 120 calendar days</td>
</tr>
<tr>
<td>Minimum mandatory advance notification</td>
<td>30 business days</td>
</tr>
<tr>
<td>Confirmation of anticipated filing date</td>
<td>30 business days&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Call for patient input issued</td>
<td>20 business days</td>
</tr>
</tbody>
</table>

<sup>a</sup> Required only if more than 30 business days advance notice was provided.

- 30 business days is the **MINIMUM** required to avoid a delay in initiation and should not be considered as the **TARGET** date
- More notification is preferred by CADTH
Reimbursement Criteria

• Effective January 2018, disclosure of requested reimbursement criteria will be mandatory for all CDR submissions and resubmissions
• Confidentially submitted requested reimbursement criteria will not be accepted by CADTH
• Implementation date selected to provide sufficient notice for applicants and to permit CADTH to modify website
• Essential to ensure that patient groups have adequate information when providing input on pending submissions
• Aligns CADTH’s CDR and pCODR submission processes
CDR Procedures and Guidelines

- Planned release in early 2018 to incorporate revisions from the ongoing CADTH consultations and other procedural initiatives
- Plan to update on more predictable schedule
- Highlights of revised versions:
  - Consolidation of CDR procedure and submission guidelines into a single document
  - Improved instructions for templates
  - Consolidation of authorization forms (less paper work)
  - Fewer specialized category 1 requirements
    - e.g., CONSORT diagrams
Collaborative Space

- CADTH will be implementing a Collaborative Workspaces secure portal to receive and exchange documents for CDR
  - Aligns with approach used in the pCODR process
- Replaces CDR’s current process of receiving submission requirements on physical storage media
- Streamline activities by moving information to a centralized, secure location with a single log-in
- Details regarding this process change will be outlined in a CDR update later this fall
- **Target implementation date of January 2018**
Reminders

• Applicants have indicated that consulting services have provided out of date templates and/or procedural advice:
  • Do not archive CADTH templates as they are subject to change.
  • Applicants should ensure templates are obtained exclusively from the CADTH website and are the latest versions posted.
• Consultants working on a CDR file are advised to copy an official contact for the manufacturer on all email correspondence with CADTH.
  • CADTH will not respond if an official contact for the manufacturer has not been copied.
• Always email requests@cadth.ca for CDR-related inquiries to ensure tracking and triage
  • Do not email individuals at CADTH regarding CDR inquiries.
Drug Portfolio Consultations

• CADTH has undertaken a number of important consultations in the past year:
  ▪ Revised submission and review process for biosimilars
  ▪ Revised therapeutic review framework
  ▪ Revised resubmission criteria
  ▪ New process for companion diagnostics
  ▪ New patient input template

• There is high level of participation in consultations
  ▪ Thank you to all stakeholders who take the time to provide feedback on CADTH’s initiatives
Resubmission Criteria Consultation

Perspective on Evidence from Non-Randomized Studies

- CADTH considers data from non-randomized studies to be particularly useful in the following situations:
  - Evaluation of endpoints requires longer-term follow-up
  - Uncertainty regarding the persistence of efficacy
  - RCT is impractical or unethical
  - RCT lacks relevant comparators (e.g., IDC required)
  - RCTs have limited external validity
  - Uncertainty regarding how drugs are used in clinical practice (e.g., dosages)
Resubmission Criteria Consultation

Proposed Eligibility Criteria for Resubmissions

• New studies in support of improved efficacy will not have to RCTs
• Any new studies must address issues in the recommendation
• CADTH may consult with expert review committee to determine if the new information addresses the issues noted in the previous recommendation
• The final decision regarding whether or not a resubmission will be accepted will be determined by CADTH. There is no provision for requesting reconsideration of the decision
• CADTH may limit the number of resubmissions that can be made within a defined period of time for a particular drug
Resubmission Criteria Consultation

Stakeholder Feedback

- General support for proposed revisions
- Applicants should be permitted to request reconsideration in the event CADTH determines that a resubmission will not be accepted for review
- NRS should be considered in submissions as well.
  - *Note: CADTH currently reviews NRS on a case-by-case basis (e.g., indirect comparisons and extensions studies)*
- NRS could facilitate coverage with evidence development
- CADTH could provide advice on the type of evidence that would be required for resubmission after a CDEC recommendation has been issued.
Resubmission Criteria Consultation

Next steps

• CADTH is reviewing stakeholder feedback
• Implementation plan is being developed
• Environmental scan
  • How is evidence from NRS considered by other HTA agencies?
  • How is evidence from NRS considered by regulatory authorities?
• Revised procedure is anticipated by January 2018
## Therapeutic Review Activities

<table>
<thead>
<tr>
<th>Year</th>
<th>Topic</th>
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<tbody>
<tr>
<td>2017</td>
<td>Drugs for type 2 diabetes: third-line therapy</td>
</tr>
<tr>
<td>2016</td>
<td>Drugs for type 2 diabetes: second-line therapy</td>
</tr>
<tr>
<td>2015</td>
<td>Anti-VEGF drugs for retinal conditions</td>
</tr>
<tr>
<td>2015</td>
<td>Drugs for pulmonary arterial hypertension</td>
</tr>
<tr>
<td>2014</td>
<td>Direct-acting antivirals for hepatitis C genotype 1</td>
</tr>
<tr>
<td>2013</td>
<td>Management of relapsing-remitting multiple sclerosis</td>
</tr>
<tr>
<td>2012</td>
<td>Antithrombotic therapy in atrial fibrillation</td>
</tr>
<tr>
<td>2012</td>
<td>DOACs for use in atrial fibrillation</td>
</tr>
<tr>
<td>2010</td>
<td>Drugs for type 2 diabetes: third-line therapy</td>
</tr>
<tr>
<td>2010</td>
<td>Biological response modifier agents in RA</td>
</tr>
</tbody>
</table>
Therapeutic Review Consultation

- Need to initiate RFA process is time consuming and less efficient
- Results in a period of time where CDR and TR recommendations are not aligned:
  - Challenging for stakeholders
  - Unclear if recommendations from TR supersede those from CDR process
Therapeutic Review Consultation

- Expanded TR process builds on strengths of the RFA and TR processes
- Clear direction whether or not TR recommendations are intended to supersede CDR recommendations
- Ensures CADTH recommendations represent the best available evidence
Therapeutic Review Consultation

- Feedback was received from industry associations (2), drug manufacturers (6), and patient groups (5)

- **Topic selection process**
  - Greater transparency in the selection of topics for TRs

- **Evidence review process**
  - Real-world evidence
  - Issues with confidential pricing agreements
  - Allow for redaction of confidential information

- **Recommendation process**
  - Request for reconsideration should be permitted
  - Revising CDR recs based on draft TR recommendations
  - Recommendation framework for TR should be developed
Therapeutic Review Consultation

- **Stakeholder feedback process**
  - Clarify patient engagement opportunities
  - Duration of stakeholder feedback opportunities
  - Disclosure of stakeholder feedback

- **Implementation considerations**
  - Concern about how existing agreements with the drug programs could be impacted

- **Next Steps**
  - CADTH is currently reviewing stakeholder feedback
  - A finalized process is anticipated in 2018
Therapeutic Review Consultation

New Opportunities for Patient Engagement

1. Patient group teleconference
2. Patient group input on therapeutic review
3. Patient group input on existing CDR recommendations (new)
4. Feedback on proposed project scope
5. Feedback on the list of included studies
6. Feedback on the draft science reports
7. Feedback on the draft TR recommendations
8. Feedback on any proposed revisions to existing CDR recommendations (new)
Biosimilars

CADTH’s Proposed Revisions to the Biosimilar Review Process for CDR and pCODR
Objective of Proposed Revision to Biosimilar Process

• To streamline approach to biosimilar reviews by providing centralized coordinating role to support improved access for patients to biosimilars working in collaboration with:
  • Health Canada
  • pan-Canadian Pharmaceutical Alliance (pCPA)
  • participating federal, provincial and territorial public drug plans
  • provincial cancer agencies
Overview of Proposed Biosimilar Process

1. Proposed Submission Requirements
   - Proposed that submitters file to CADTH shortly after making a submission to Health Canada
   - Proposed that submitters would be required to provide:
     i. Select submissions requirements
     ii. A completed Biosimilar Summary Dossier Template

2. Stakeholder Participation
   - Proposed that stakeholder perspectives and experiences are incorporated
Overview of Proposed Biosimilar Process (Cont’d)

3. CADTH Appraisal

- Proposed that the Biosimilar Summary Dossier will **not** be brought forward to CADTH’s expert review committees.
- Proposed that CADTH would provide commentaries and analyses on sections of the Dossier and work closely with Health Canada to include a summary of the market authorization of the biosimilar under review.
Overview of Proposed Biosimilar Process (Cont’d)

4. Transparency

• Proposed that Biosimilar Summary Dossier will be posted on the CADTH website

• Proposed that information provided in the Dossier be fully disclosable
Who Participated in the Consultation?

- **Patient Groups**: 7
- **Clinicians**: 3
- **Jurisdictions**: 1
- **Industry Associations**: 5
- **Individual Manufacturers**: 6
- **Consultants**: 1
- **Private Insurance Association**: 1

Legend:
- Blue bars represent the number of participants.
- Red bar indicates a joint patient group submission.
Next Steps

- Complete review of all comments
- Map out clear process based on stakeholder comments
- Communicate back to all interested parties
- Evaluation component after a pre-defined period of time
pCODR Updates
pCODR Expert Review Committee (pERC) Membership

- Maureen Trudeau (Chair)
- Catherine Moltzan (Vice-chair)
- Kelvin Chan
- Flay Charbonneau (New)
- Matthew Cheung
- Winson Cheung (New)
- Avram Denburg (New)
- Mike Doyle (New)
- Craig Earle
- Leela John (New)
- Anil Joy
- Christine Kennedy (New)
- Cameron Lane (New)
- Valerie McDonald
- Carole McMahon
- Marianne Taylor
pCODR—Volume of Submissions Received

Submissions

<table>
<thead>
<tr>
<th>Year</th>
<th>Submissions</th>
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<tbody>
<tr>
<td>2012</td>
<td>13</td>
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<tr>
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<td>2014</td>
<td>15</td>
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<td>2015</td>
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</tr>
<tr>
<td>2016</td>
<td>23</td>
</tr>
<tr>
<td>2017</td>
<td>24</td>
</tr>
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pERC Recommendations

pCODR has issued 88* “Notification to Implement” as of June 30, 2017

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Percentage</th>
</tr>
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<tbody>
<tr>
<td>9 (10%) recommend to reimburse</td>
<td>10%</td>
</tr>
<tr>
<td>59 (68%) recommend to reimburse</td>
<td>68%</td>
</tr>
<tr>
<td>with clinical criteria and/or conditions</td>
<td></td>
</tr>
<tr>
<td>19 (22%) do not recommend to</td>
<td>22%</td>
</tr>
<tr>
<td>reimburse</td>
<td></td>
</tr>
</tbody>
</table>

*Note: pERC issued notification for 1 Request for Advice
Health Canada/pCODR Pilot
What is the Health Canada/pCODR Pilot?

• Joint initiative to improve the sharing of information between both groups

• Objectives:
  1. Strengthen collaboration between Health Canada and CADTH through the pCODR program to leverage the work of each organization, enhance efficiencies, and facilitate workload management
  2. Explore opportunities to develop a more integrated model for drug review in Canada
Scope of the Pilot

• Oncology drugs (i.e., eligible for pCODR review)
• Drugs that were already in Health Canada’s current workload prior to July 2017
• Only within the Bureau of Metabolism, Oncology, and Reproductive Science (BMORS) division of Health Canada
Highlights of Lessons Learned to Date…

• Improved understanding of Health Canada/pCODR processes
• There are many components that Health Canada and pCODR cannot control
• Importance of sharing information early to reduce risk of potential delays
• Different approaches to transparency
Next Steps

• Joint Health Canada/pCODR Presentation at the DIA (Drug Information Association) conference later this month
• Define and demonstrate how the successes and lessons learned from the pilot can be operationalized into the processes of each respective program
• Engagement with stakeholders
CADTH and Canadian Cancer Action Network (CCAN) HTA Project Collaboration

Continued enhancement of patient group involvement in HTA processes for oncology drugs in Canada
CADTH and CCAN Collaboration

Worked together on the following key resources:

   - A “Canadian first” guide to provide patient advocacy groups instructions on best practices for completing patient input submissions for cancer drug review
   - Then developed narrated slide decks to accompany the Guide
2. A series of joint workshops to provide orientation and training to the participating patient community/patients with respect to the process
3. Launched a short-term (6 month) pilot for a dedicated ‘live’ resource to support patient groups’ participation in pCODR process
4. Developed a comprehensive Health Technology Assessment (HTA) Evaluation Framework
   - to further examine the impact of patient group involvement in the decision-making process for oncology drugs in Canada (in partnership with Canadian Centre for Applied Research in Cancer Control)
HTA Project Collaboration

Objectives

1. Assisting patient groups to easily navigate the evidence submission process for cancer drug reviews.
2. Enhancing the quality of evidence submissions.
3. Fostering enhanced engagement of patient groups in the pCODR process.
Ongoing Collaboration

• Active implementation of the HTA Evaluation Framework:
  1. Established a multi-stakeholder HTA Project Advisory Committee and Content Expert Team to inform the design and development of key HTA tools and initiatives targeted at patients and patient groups
  2. Qualitative study of patient groups
  3. Launched post-submission input survey for patient groups providing input on pCODR submissions
  4. Planning to co-host HTA workshop for patients and patient groups in early 2018
Cancer Drug Pipeline Information for Patient Groups

- Launched a new searchable cancer drug information pipeline database (July 27th)
  http://www.ccanceraction.ca/pipeline/
Post-Survey Questions for Patient Groups

• Launched survey (August 17th)
• Survey link available through automated email reply after a patient group has filed a patient evidence submission with the pCODR program
Post-Survey Questions for Patient Groups

1. How did you hear about the drug pending review? Please check all that apply.

2. Do you prepare submissions for every drug that affects your patient population?

3. What resources have you used (either for this current or past submissions) when making a submission to pCODR.

4. Did you experience any challenges with preparing your submission to pCODR?

5. Please provide one (1) improvement that the pCODR program could make to the submission process.
What’s Next?

- Planning workshop for early in new year
- Working with ARCC and HTA Project Advisory Committee and Content Expert Team to develop proposed criteria to assess a high quality patient input submission
  - Stakeholder consultation on draft criteria
Patient Engagement Update
Overview

• Input submissions posting
• Patient input template
• Collaboration and outreach
Posting of Input Submissions

• As of September 1, 2017 all patient input submissions shared on CADTH website
• Individual permission no longer sought for each submission
• Patient groups can continue to request redaction of any information that may identify patients in original or summary
Drug Formulary News: 
Patient Input Template Revisions

- Patient input submission template released early 2017
- Currently in use, with no issues reported by patient groups
Collaboration

Patient Community Liaison Forum
www.cadth.ca/cadth-patient-community-liaison-forum

• In-person meeting in Toronto, October 4, 2017

Patient engagement in health technology management

• Proposed revisions to the patient input process for biosimilars

• Patient group participation at 2018 CADTH Symposium
Collaboration

- CADTH Symposium – April 15-17, 2018
  Halifax
- Health Technology Assessment International (HTAi) June 1-5, 2018 – Vancouver
Open Forum
Wrap Up
CADTH LECTURE SERIES

Canada's Opioid Crisis: The Changing Reality Between Exam Rooms and Ivory Towers

Dr. Hakique Virani

October 12, 2017
2:00 p.m. to 3:00 p.m. EDT
Dow's Lake Court Conference Centre,
865 Carling Avenue, Ottawa, Ontario

cadth.ca/lectures
Exploring Canada’s Early Scientific Advice Services with CADTH and Health Canada

WEDNESDAY, OCTOBER 18, 2017 AT 1:00 PM (EDT)

Lindsay Blaney, Senior Advisor to the Director General, Biologics and Genetic Therapies Directorate, Health Products and Food Branch, Health Canada
Amy Sood, Lead, Scientific Advice Program, CADTH
Don Husereau, Health Policy and Technology Assessment Consultant

WEBINAR REGISTRATION:  http://www.cahr-acrss.ca/
2018 is going to be a big year for HTA in Canada

Halifax, NS
2018 CADTH Symposium
April 15 to 17, 2018
cadth.ca/symposium2018

Vancouver, BC
HTAi 2018 Annual Meeting
June 1 to 5, 2018
htai.org

Two world class Health Technology Assessment conferences — one on the west coast, one on the east coast.
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