Exploring Canada’s early scientific advice:

Global and Canadian context, CADTH and Health Canada perspectives

October 18, 2017
Today’s participants

**Moderator**

Bill Dempster  
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**Panelist**

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What we’ll discuss

• Reviewing the global and Canadian contexts
• Close up overview of how the processes work
• How to engage with Health Canada and CADTH to ensure they are meeting the needs of manufacturers and health systems
• Panelist perspectives
• Discussion and Qs and As
Early Scientific Advice –
International Perspectives

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Why Early Scientific Advice?

- ESA
- Health system value?
- Clinical development program
- Regulator
- Payer / HTA
- pCPA
- Reimbursed, marketed product
Why do companies say they use ESA?

- Lack of precedence in HTA / novelty
- Competitive advantage
- Insights into market access opportunities
The Past and Future of Constructive Technology Assessment

JOHAN SCHOT and ARIE RIP

ABSTRACT

Constructive technology assessment (CTA) is a member of the family of technology assessment approaches, developed in particular in the Netherlands and Denmark. CTA shifts the focus away from assessing impacts of new technologies to broadening design, development, and implementation processes. Explicit CTA has concentrated on dialogue among and early interaction with new actors. The idea has been taken up by actors other than governments (consumers, producers). CTA implies a modulation of ongoing technological developments, and an understanding of the dynamics of such modulation is used to identify and briefly discuss three generic strategies for CTA: technology forcing, strategic niche management, and loci for alignment. Modulation activities are to be located in the broader issue of how our societies handle new technology at all. The established division of labor between promotion and control should be mitigated by sociotechnical criticism. This underlines the need for reflection on role and value profile of CTA agents. © 1997 Elsevier Science Inc.

Introduction

In the three decades since the first articulation of technology assessment (TA), a whole family of TA approaches has emerged. Smits, Leyten, and Den Hertog [1] distinguish awareness TA, strategic TA, and constructive TA. Grin and van der Graaf [2] emphasize interactive TA, a more symmetrical version of what used to be called participatory TA [3]. This family of approaches is characterized by its commitment to what we see as an overall TA philosophy: to reduce the human costs of trial and error learning in society’s handling of new technologies, and to do so by anticipating potential impacts and feeding these insights back into decision making, and into actors’ strategies.

One member of this family of approaches is constructive TA (CTA), which origi-
**International/Non-governmental**

- Tapestry
- Green Park Collaborative International
- IMI (Innovative Medicines Initiative, an EU Public-Private partnership) - Year of inception: 2010 (now closed)
- Year of inception: 2011
- Year of inception: 2015

**Europe**

- United Kingdom (NICE)
- Sweden (TLV-MPA)
- Netherlands (ZINL, ZINL-CEB) - Tapestry: 2010 then EUnetHTA
- Spain (Regional)
- Italy (AIFA)
- EUnetHTA pilots - Year of inception: 2011-2015
- Germany (GBA)
- France (HAS)
- European Commission - Year of inception: 2012
- Year of inception: 2012
- Year of inception: 2014

**North America**

- FDA/CMS Parallel Review - Year of inception: 2010
- Green Park Collaborative (USA) - Year of inception: 2011
- MaRS EXCITE (Canada) - Year of inception: 2011
- Canada (CADTH) - Year of inception: 2015
## Different approaches within ESA programs

<table>
<thead>
<tr>
<th>When advice sought</th>
<th>Content addressed</th>
<th>Format given</th>
<th>Who is involved?</th>
<th>Nature of advice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre phase III</td>
<td>Clinical</td>
<td>Written / verbal</td>
<td>Regulator (tri-partite)</td>
<td>Binding</td>
</tr>
<tr>
<td>Post phase III</td>
<td>Economic</td>
<td>Dialogue or information-only</td>
<td>Other HTA bodies</td>
<td>Confidential</td>
</tr>
<tr>
<td>Pre-application</td>
<td>Other?</td>
<td></td>
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*Content.* 17-10-20
Other factors to consider

• **Cost of applying**
  – Internationally, 3K to 84K depending on scope

• **Timing of advice**
  – 8 – 26 wks

• **Requirements for application**
  – Meetings / scheduling
  – Briefing book
Further information


Who needs (early) advice? You do!

November 3, 2016

With increasing emphasis on real-world evidence in the drug approval process, Don Husereau examines the current status of, and future prospects for, Health Technology Assessment Early Scientific Advice programmes.
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[Link to COI]
CADTH Scientific Advice

Advice on early drug development plans from a Canadian health technology assessment (HTA) perspective

- Non-binding
- Confidential
- Cost-recovery

For Industry
- Reduce uncertainty

For Drug Benefit Plans
- Recommendations based on more relevant evidence

For Patients and Clinicians
- Timely access for patients
Standard Timeline

- 4 weeks: Online Application
- 14 weeks: Briefing Book
- 4 weeks: SCIENTIFIC ADVICE MEETING
- Written Record of Scientific Advice

$65,000 to $100,000 CAD plus taxes
CADTH Scientific Advice Team

Record of Scientific Advice

Clinical Expert 1

Clinical Expert 2

Health Economist

Patient Interview

CADTH Scientific Advisor
Listening to Stakeholders

Semi-structured interviews conducted July to October, 2016

Key Interview Findings:

Opportunities For Improvement

Scope

Flexibility

Regulatory/HTA bodies
Scope: Early Development Plan

- CADTH’s Scientific Advice Program
  - Current focus is on advice prior to initiation of Phase III or Pivotal trials
  - Eligibility expanded to earlier advice prior to initiation of Phase II trials
Flexible Program Offerings

- Customized timelines
- More timely advice for smaller requests
- Advice at multiple touch points

Please inquire: scientificadvice@cadth.ca
**Timely Advice for Smaller Requests**

**Standard Timeline**

- **4 weeks**
  - Online Application
  - Briefing Book

- **14 weeks**
  - Scientific Advice Meeting

- **4 weeks**
  - Record of Scientific Advice

**Option for Smaller Requests**

- 2 to 3 clinical questions
- 1 clinical expert
- Patient interview
- No F2F Scientific Advice meeting
- Lower fee

10-12 weeks
Collaboration with Health Canada

A total of 4 applicants provided consent

Health Canada observed F2F Scientific Advice Meeting
  1. Dec 2016: biologic drug

Health Canada observes F2F & preparatory meetings
  2. Sept 2017: oncology drug (non-biologic)
  3. Nov 2017: biologic drug
  4. Nov 2017: biologic oncology drug
Future Collaboration: Health Canada

- Valuable learning experience with Health Canada participating in preparatory team meetings

- Next steps:
  - CADTH will participate in the Early Parallel Scientific Advice Project, lead by Health Canada
CADTH SCIENTIFIC ADVICE

CADTH.CA/SCIENTIFICADVICE

SCIENTIFICADVICE@CADTH.CA
Outline

- Canada
- Internationally
- Regulatory Review of Drugs and Devices (R2D2)
- Health Canada Early Parallel Scientific Advice Project
  - Description
  - From, To
  - Opportunities
  - Next Steps

- Healthcare System Need
  - Concept
  - Definition
Early Scientific Advice - Canada

- Health Canada
- CADTH
- INESSS
Early Scientific Advice - Internationally

- USFDA
- EMA
- Australia
- UK
Health Canada’s plan for transformation

Objective: An agile regulatory system that supports better access to therapeutic products based on healthcare system needs

- Expanded collaboration with health partners
  - Alignment of the HTAs (CADTH & INESSS) Reviews with HPFB Review
  - Implementing a Mechanism for Early Parallel Scientific Advice
  - Use of Foreign Reviews/Decisions
  - International Collaboration and Work Sharing in Reviews

- More timely access to drugs and devices
  - Expansion of Priority Review Pathways
  - Improving Access to Biosimilars and Biologics
  - Improving Access to Generic Drugs
  - Building Better Access to Digital Health Technologies
  - Pre-Submission Scientific Advice for Medical Devices
  - Special Access Programme (SAP) Renewal

- Modern and flexible operations
  - Overview of Common Submission Intake (IP400)
    - Appropriate cost recovery framework
    - Public Release of Clinical Information

- Enhanced Use of real-world evidence
  - Leveraging Data for Assessing Drug Safety and Effectiveness
  - Strengthening Post-market Surveillance of Medical Devices
Early Parallel Scientific Advice

Description of Project

- HTA and Regulator
- Provide Early Parallel Scientific Advice to Sponsor
- Single Drug Development Plan
- Generates More Robust, Better Quality and Relevant Evidence
- Satisfies the Needs of Both the HTA and the Regulator

Health Canada Early Scientific Advice Process
Early Parallel Scientific Advice

FROM

- Evidence does not adequately support regulatory authorization or HTA recommendation
- Difficult, controversial decisions
- Regulator and HTA reviews not sufficiently aligned

TO

- More robust, higher quality and relevant evidence
- Improved likelihood of positive decisions/recommendations
- Single drug development plan
- Provides for clearer, more solid decisions from the Regulator and HTA
- Facilitation of the review alignment
- Earlier access to reimbursable drugs
Early Parallel Scientific Advice - Opportunities

- Reduces Uncertainties for Industry
- Patient Involvement
- Harmonization of Branch Processes
Early Parallel Scientific Advice – Next Steps

- Development of Issue Analysis Summary
- Internal, external consultation
- Pilot
- Issuance of Guidance Document
- Implementation of Process
Healthcare System Need
Healthcare System Need - Concept

• The current drug review process at Health Canada is designed to assess drug safety, efficacy and quality with limited ability to prioritization based on healthcare system need.

• Health Canada policy *Priority Review of Drug Submissions* does allow for shortened timelines for certain drug reviews, but only those that treat serious, life-threatening conditions or diseases. The needs of the healthcare system extend beyond this.
Healthcare System Need - Definition

Some possible criteria include *these are just a few ideas that have been provided to us by stakeholders*:

• Unmet need:
  – Serious or life-threatening conditions that fill an unmet medical need
  – Significant improvements to quality of life (e.g., *easier to administer formulation such as a tablet versus an injection*]
  – Rare diseases (e.g., *orphan drugs*)
  – Special populations: Pediatrics, Indigenous health needs (i.e. diabetes)
  – Off label use

• Cost effectiveness:
  – Savings to the healthcare system
  – Savings to public drug plans [e.g., *biosimilars and new generics*]

• Emergency Use:
  – Same profile as authorized drugs with experienced, ongoing supply issues (e.g., *therapeutic alternatives to drugs in shortage*)
  – Emerging or anticipated public health need (e.g., *antimicrobials*)
  – 2 years or more on Health Canada’s List of Drugs for Urgent Need
Healthcare System Need - Input

Please send your input to

michelle.remillard@canada.ca

Thank you!
Discussion and Qs and As

Themes from today’s discussion

• Global research agendas and timing
• Patient reported outcomes and quality of life data
• Adaptive clinical trials and earlier data
• Real-world evidence
• Longer-term impacts on / benefits for payers, funders and patients/caregivers
• Engagement with stakeholders going forward
Thank you!!