# List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BC</td>
<td>British Columbia</td>
</tr>
<tr>
<td>CADTH</td>
<td>Canadian Agency for Drugs and Technologies in Health</td>
</tr>
<tr>
<td>CDR</td>
<td>Common Drug Review</td>
</tr>
<tr>
<td>CEDAC</td>
<td>Canadian Expert Drug Advisory Committee</td>
</tr>
<tr>
<td>CFHI</td>
<td>Canadian Foundation for Healthcare Improvement</td>
</tr>
<tr>
<td>COI</td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td>DBC</td>
<td>Drug Benefit Council (BC)</td>
</tr>
<tr>
<td>DPAC</td>
<td>Drug Policy Advisory Committee</td>
</tr>
<tr>
<td>FTE</td>
<td>Full-Time Equivalent</td>
</tr>
<tr>
<td>FWG</td>
<td>Formulary Working Group</td>
</tr>
<tr>
<td>HTA</td>
<td>Health Technology Assessment</td>
</tr>
<tr>
<td>INESSS</td>
<td>L’Institut national d’excellence en santé et en services sociaux</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
</tr>
<tr>
<td>PBAC</td>
<td>Pharmaceutical Benefits Advisory Committee (Australia)</td>
</tr>
<tr>
<td>pCODR</td>
<td>pan-Canadian Oncology Drug Review</td>
</tr>
<tr>
<td>SMC</td>
<td>Scottish Medicines Consortium</td>
</tr>
</tbody>
</table>
Contents

Context and Methodology

Analysis
• Current state analysis of the Common Drug Review (CDR) patient input process
• CDR stakeholder — survey data analysis
• Comparative analysis — local and international peers

Assessment

Recommendations
CADTH initiated a patient input program as part of the CDR process in May of 2010 in response to requests from several key stakeholders.

- CADTH agreed to evaluate the program after 12 to 18 months of having it in place; given that no standard patient input process exists across HTA agencies, it was expected that changes would need to be made after the evaluation.

An initial high-level assessment of the program was undertaken and reported as part of the broader, external evaluation of CADTH conducted by SECOR at the end of 2011.

- Key finding: Patients, committee members, stakeholders, manufacturers, and CADTH staff are not fully aligned on the objective of the patient input process, and are unclear as to what the impact has been.

SECOR was engaged in April of 2012 to examine CADTH’s Patient Input Program in more depth, and to compare CADTH’s approach to international peer health technology assessment (HTA) agencies.

- This report summarizes key findings and potential improvements for CADTH’s consideration.

**Key messages from the analysis:**

- CADTH’s patient input program is roughly on par with, or more developed than, most of its peers. NICE and pCODR have significantly more evolved programs on several dimensions.

- CADTH could implement best practice learnings from international peers to address several patient input process design and execution gaps identified by key stakeholders.

- However, a more fundamental issue needs to be addressed first: whether stakeholders are aligned on the purpose, value, and credibility of soliciting patient input as evidence in making drug listing recommendations.
SECOR evaluated CADTH’s patient input process along three main dimensions and several sub-dimensions:

**Evaluation Vectors**

<table>
<thead>
<tr>
<th>Philosophy and Goal</th>
<th>Underlying Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Importance to decision-making</td>
<td>How is patient data weighted relative to clinical and economic evidence?</td>
</tr>
<tr>
<td>How aligned are key drug review decision-makers and stakeholders regarding the role of patient input?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Design</th>
<th>At what stage(s) of the review process is patient input incorporated?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage of incorporation</td>
<td>What types of patient entities are able to provide input? What form does the input comprise?</td>
</tr>
<tr>
<td>Mechanisms of solicitation</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Process</th>
<th>How comprehensively can patients provide their data through the submission form?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexibility of input</td>
<td>Does the time allotment meet the timelines of the review? Is the time allotment reasonable for patient groups to submit the data?</td>
</tr>
<tr>
<td>Time allotment</td>
<td>How accessible and user-friendly is the process?</td>
</tr>
<tr>
<td>Utility</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Inputs</th>
<th>Are there sufficient data points to inform decision-making?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breadth of data points</td>
<td>How relevant/useful is the collected data in informing decision-making?</td>
</tr>
<tr>
<td>Type/quality of data gathered</td>
<td>What types of support/communication mechanisms are available for patient groups (before, during, and after the process)?</td>
</tr>
<tr>
<td>Quality control</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outputs</th>
<th>How is the evidence incorporated into decision-making?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorporation of evidence</td>
<td>How are those who make a submission kept abreast of the process?</td>
</tr>
<tr>
<td>Transparency of decision-making</td>
<td>How are key stakeholders (including patient groups who have submitted) made aware of how their information was used for decision-making?</td>
</tr>
</tbody>
</table>

1 Written submission process only
Methodology

Inputs

- Data/document review
  - including phase I evaluation interview notes and data
- Key informant interviews
  - Elaine MacPhail (CADTH)
  - Karen Facey (Evidence-based Health Policy Consultant, Scotland)
  - Judith Glennie (J.L. Glennie Consulting Inc.)
- HTA Agency comparison
  - pCODR (Mona Sabharwal)
  - INESSS (Lucie Robitaille)
  - Australia PBAC (Janet Wale)
  - NICE (Lizzie Amis)
  - Scotland SMC
  - British Columbia, Ontario
- Survey data
  - Patient group survey (29)
  - Industry survey (17)
  - CEDAC members survey (8)
  - CDR reviewer (13)
- Literature (grey, published)

Analysis

Philosophy and Goal

Design

Execution

Process

Inputs

Outputs

Transparency of the process

Key Findings

Comparative Analysis

Recommendations for Improvement

The review was conducted over 5 weeks, from April 10 to May 4, 2012
Contents

Context and methodology

Analysis
• Current state analysis of CDR patient input process
• CDR stakeholder — survey data analysis
• Comparative analysis — local and international peers

Assessment

Recommendations
Analysis: Overview of Current State of CDR Patient Input Process

**Philosophy and Goal**

**Importance to decision-making**
- Objectives
  - Seek information via Canadian patient groups
  - Respect existing review time frames for CDR
  - Systematically incorporate input throughout the process

**Design**

**Stage of incorporation**
- Patient input is collected at the beginning of the CDR process and is used for protocol development, incorporated in the draft and final report, and presented by laymen representatives (CEDAC public members)
- The input is not provided/incorporated regarding the draft report

**Mechanisms of solicitation**
- Patient input currently comes from patient group written submissions to CADTH

**Execution**

**Flexibility of input**
- Patient groups can submit information up to 6 pages; there is no word limit to questions included in the template

**Time allotment**
- Current patient input process respects the existing CDR timeline

**Utility**
- A section on a CADTH web page is dedicated for patient input
- The CDR review process is published on the CADTH website
- The submission document is to be downloaded by patient groups, completed, and submitted online or faxed

**Process**

**Inputs**

**Outputs**

**Breadth of data points**
- Number of patient submissions range from 0 to 9 per review with an average of 1.8 submission and a median of 1 submission
- CADTH does not accept individual patient input

**Type/quality of data gathered**
- Patient input currently comes from patient group written submissions to CADTH
- Submission form has questions in a similar structure as some other HTA agencies

**Quality control**
- A guidance document is available on the CADTH website
- CADTH organized one patient group training session in 2011
- Elaine has participated in ~5-6 initiatives where she spoke about CADTH patient input process
- No formal feedback mechanism in place
- No dedicated FTE to patient initiative
- Contact information is posted on the CADTH website should patient groups have any questions

**Incorporation of evidence**
- Information such as issues or outcomes of importance is used by CDR reviewers to develop protocol
- Patient input information is summarized in its own section in the clinical report
- Patient input is included in the CEDAC Brief, is presented by laymen representatives at the CEDAC meeting, and the committee considers the patient input with other evidence to make a decision

**Transparency of decision-making**
- Patient input is summarized in a section of the final recommendation document, and may be included in the recommendation and reasons for recommendation section. The final recommendation is posted online

Source: CADTH website, interview with Elaine MacPhail, SECOR Analysis
Analysis: Historical View of CDR Patient Input Process

May 2010

Patient input process launched

2011

5/2011 to 9/2011
CADTH conducted a survey on patient input process, feedback gathered from patient groups, CEDAC members, CDR reviewers, industry

9/2011 to 12/2011
CADTH Phase I Evaluation, including interviews and data review for patient input process (SECOR)

2012

4/2012 to 5/2012
Patient input process External Review (SECOR)

Number of patient input submissions by month from June 2010 to March 2012*


3 8 1 5 1 6 5 5 1 0 7 1 0 2 7 6 3 0 4 5 5

Source: SECOR Analysis, CADTH internal data

*Note: The number of patient submissions is influenced by the number of CDR submissions, and number of patient groups that may be impacted by the drug.
Analysis: Overview of the CDR Patient Input Process

**CDR Process**

1. **Receipt of Drug submission**
2. **Reviewer report developed by Review Team**
3. **CEDAC Brief**
   - reviewers’ reports, manufacturer’s comments, patient input
4. **Initial CEDAC Recommendation**
   - sent to Drug plans, DPAC, and manufacturers
5. **Embargo period**
6. **Reconsideration / Resubmission based on Reduced Price**
7. **Final CEDAC Recommendation**

**Patient input**

- **No Requests Addressed Request for Clarification**
- **Total Review Time**
  - 23.6-35 weeks

**Groups subscribe to “Calls for Patient Input” e-alert service**

- Manufacturers provide advance notification of a pending CDR submission

- **Yes**
  - “Calls for Patient Input” are posted when advance notification is received

- **No**
  - “Calls for Patient Input” are released when CDR submission is received

**Information in the call for patient input includes the drug name (generic and brand), the manufacturer, the indication, the project number, the date the submission was received, and the deadline for patient input**

**Patient groups make a submission**

- **Up to 25 business days**
- **15 business days**

**Manufacturer provide advance notification of a pending CDR submission**

**Patient groups are requested to provide their input using a template and submit the information online or by fax**

*Source: CADTH website; interviews with internal CADTH staff and external stakeholder groups*
Across 52 drug reviews from May 2010 to March 2012:

- 25% did not receive a patient submission
- 38% had 1 patient submission
- 30% had 2 to 4 patient submissions

**Number of patient input submissions received across all drug reviews to date**

*Review number – all patient input submissions from 21 May 2010 – 31 March 2012*

Source: CADTH Internal Data, SECOR Analysis
Contents

Context and methodology

Analysis

- Current state analysis of CDR patient input process
- **CDR stakeholder — survey data analysis**
- Comparative analysis — local and international peers

Assessment

Recommendations
Analysis: Comprehensive Survey Data was Analyzed

In September 2011, CADTH surveyed four groups of stakeholders involved in the patient input process (patient groups, industry, CEDAC members, and CDR reviewers). The questions were tailored based on touch points the stakeholders have in the process. Surveys contained multiple choice questions, as well as open-ended questions. Response rates were as follows:

- Patient (29)
- Industry (17)
- CEDAC members (8)
- CDR reviewers (13)

The answers are synthesized and mapped to the framework below.

Notable strengths of current process

Disconnects in opinion

Stated opportunities for improvement

Philosophy and Goal

Design

Execution

Process

Inputs

Outputs
**Analysis: Survey Results — Philosophy and Goal**

Although most CEDAC members and CDR reviewers agree with the rationale for a patient input process, there continues to be skepticism about the objectivity of the patient voice.

### Notable Strengths of Current Process

- Most members believe that the concept of having patient submissions is important
  - "I believe that patient-related outcomes are important and should be highlighted"
- Most believe that patient input provides information that is not otherwise available
- The majority said patient input has enhanced CDR review
  - "Seems to be adequately described during CEDAC meetings"
  - "The patient input information simply allows us to be more confident in stating that a given outcome is of importance to patients, rather than speculating that it is"
  - "We are interested to know the patients’ opinions, experiences, etc...we cannot critically appraise that in the same way"
- Most believe patient input helps reviewers gain more understanding on how treatments work in real life: logistically and in terms of efficacy
- Most said patient input is fairly or very relevant for CDR reports
  - ~70% feel the information from patient submissions is not otherwise obtainable
- The majority of reviewers are comfortable with using qualitative data from patient submissions. Reviewers:
  - Believe that expert opinion and evidence-based information can compliment patient input
  - Understand the context of patient input and will not mistake for data obtained from clinical trials
  - Can use patient input for guiding context

### Disconnects in Opinion

- 5/8 members feel patient submissions play an adequately or fairly meaningful role in decision-making, while 3/8 felt patient submissions do not play a very meaningful role
- 3/7 are not very or not at all comfortable using the qualitative patient submissions to inform recommendation
- Mixed opinions on integration of patient input:
  - "I’m not sure trying to integrate patient values, which are subjective, into a very objective and structured systematic review...is the best approach; perhaps a separate document that deals only with patient input could be part of committee’s briefing materials..."
  - "It is very challenging to integrate patient values when often industry has not captured this type of information in their clinical trials"
- 3/7 CEDAC members are not at all or not very comfortable in using qualitative patient submissions
  - "Integration of patient view should be limited to providing context to clinical and cost evidence...recommendations should continue to be based on objective clinical and cost-effectiveness data"
- 8/15 do not feel patient-important outcomes identified through the patient input process will influence clinical trial design, 3 reported it will substantially influence the design
  - "Manufactures really need to receive clearer signals from CDR on the impact that the inclusion of such outcomes will have on their recommendations"

### Stated Opportunities for Improvement

- Most do not believe that patient input has enhanced CDR
- Most do not think patient input has increased transparency, fairness, and objectivity of the drug review process
- Most say patient submissions have little influence on their final voting decision
- Most believe that there is a innate subjectivity of inputs from patient groups
  - "I’m not sure how well or how consistently they truly represent the individual issues or concerns"
- Most do not think patient submissions represent the majority view of patients and caregivers, and the minority perspective of important subgroups
  - "The information via the public members has not struck me as true patient input but rather as another selling avenue from companies"
  - "Not sure that patient evidence should be given much weight versus objective clinical cost data. It is inherently subjective and biased: no patient or patient group will ever not want access to a new drug"
- Patients also question the objectivity of the reviewer
  - "I would like to see full disclosure of all possible biases for stakeholders in the CADTH process...e.g., salary from cancer agency, public drug program, government...that should be equally declared"
  - "The guidance document places far too much emphasis on the bias of pharmaceutical funding. Perhaps this concern...can be approached in a different way that does not immediately come off as an assault on the integrity of patient organizations"

**Source:** CADTH Survey; interviews with subject matter experts and stakeholders, SECOR Analysis
CDR reviewers and CEDAC members believe that patient information has impacted various stages of the CDR review. Most agree that additional stakeholders such as individual patients/caregivers/professionals could/should provide input; however, there is no clear inclination toward any particular group(s).

### Notable Strengths of Current Process
- 70% feel patient information is relevant for protocol-building
- 76% feel patient information is relevant for contextualizing clinical and economic data
- 86% agreed patient input contributed to protocol development
- 71% agreed that presentation by public members at CEDAC meeting contributed to CDR review
- 86% agreed that reference to patient input in the CEDAC recommendations and reasons document contributed to CDR review

### Disconnects in Opinion
- High proportion agree that groups/individuals (such as individual patients/caregivers/professionals and health charities) could make submissions, while some noted that they feel patient groups are the best sources of input.
- No majority agreement on whether alternative formats such as survey, patient preference ranking, target questionnaire, or testimonials would be the most conducive to gathering valuable/objective patient information.
  - "I think the use of specific and standard questions which are aimed at views of the entire patient population would be good"
  - "I would avoid individual patient input (presumably, their information is captured overall by querying patient groups)"
  - "A target questionnaire would introduce potential for bias"
  - "I think that surveying patient groups will capture information most relevant to patients"
  - "My preference is to incorporate a survey"
- 5/7 agree that CADTH should allow other stakeholders to provide patient input, and the most relevant, alternative sources of information include individual patients, caregivers, and health care professionals, but no clear inclination toward any particular group.
- 4/7 do not think patient input contributes to contextualization of data.

### Stated Opportunities for Improvement
- Some would like to have a patient advisory committee that reports to CADTH executives.
- Some feel it may be valuable to have health care professionals who have hands-on expertise provide input.
- "We need more patient input versus input from patient groups”
- HTAs should conduct their own research to reduce the tendency of bias.
- Most do not think patient submissions represent the majority view of patients and caregivers and the minority perspective of important subgroups.

Source: CADTH Survey, interviews with subject matter experts and stakeholders, SECOR Analysis
Most are satisfied with the utility of the submission form and with the CADTH website; however, patient groups noted some opportunities for improvement. Opinions are mixed (more say “no”) on whether groups with conflict of interest should be managed differently compared with declarations by other persons involved in the CDR process.

### Analysis: Survey Results — Execution of Submission Process (I)

<table>
<thead>
<tr>
<th>Utility and Flexibility of Input</th>
<th>Notable Strengths of Current Process</th>
<th>Disconnects in Opinion</th>
<th>Stated Opportunities for Improvement</th>
</tr>
</thead>
</table>
| **Submission Form**             | • Most felt the submission template allowed the patient group to describe the issues/outcomes that are important to the majority of patients in the group  
                                   • “We are able to fit all of the information we wish to include into the template” | | • Some said the submission form is not long enough  
                                   • “Some of the questions are more geared to physical impairments than mental conditions”  
                                   • Some said the submission form is not long enough |
| **Website**                     | • Most groups are fairly or very satisfied with the accessibility of the website | | • Some would like to see a better navigation structure on the CADTH website  
                                   • Some would like CADTH to send a receipt when a submission is received  
                                   • Some would like CADTH to send disease-specific e-alerts |
| **Management of Conflict of Interest** | | | • Mixed opinions (with slightly more numbers say “no”) on whether groups with conflict of interest should be managed differently compared with declarations by other persons involved in the CDR review process |
|                                 | | | • "Move conflict of interest statements to the top of the section" |

**Source:** CADTH Survey, interviews with subject matter experts and stakeholders, SECOR Analysis
Patient groups have commented that there is not enough time to complete the submission. Industry groups suggest it is possible to provide more advanced notice to patient groups.

### Stated Opportunities for Improvement

- Large proportion indicated that they do not have enough time to complete a submission.
- One group noted that lack of resources is a major reason to not make submissions in a timely manner.
- Some suggested that it is possible to provide more advanced notice to patient groups.
- Some respondents are aware that the timeline for submission is short and suggested that longer advance notice would give patient groups more time to complete the submission.
- Some commented that there is perhaps not enough time for patient groups to collect and submit input.

### Time Allotment

<table>
<thead>
<tr>
<th>Time Allotment</th>
<th>Patient</th>
<th>CEDAC members</th>
<th>Key informants</th>
<th>Industry</th>
<th>CDR reviewers</th>
</tr>
</thead>
</table>

Source: CADTH Survey, interviews with subject matter experts and stakeholders, SECOR Analysis
The quality of submissions are variable: 70% of CDR reviewers feel the information from patient submission is not otherwise obtainable; 5/7 CEDAC members feel the information collected is adequately or fairly relevant for making a recommendation. Patient groups see value in having forums for in-person discussion such as presentations, focus groups, and direct conversations.

### Notable Strengths of Current Process
- 70% feel the information from patient submissions is not otherwise obtainable
- 5/7 feel the information collected is adequately or fairly relevant for making a recommendation
- Most agree that patient information elicits the most relevant patient values and preferences

### Disconnects in Opinion
- Mixed opinions whether CADTH should ask specific questions for each review
- Some information may not be relevant
  - “Testimonials are not useful”

### Stated Opportunities for Improvement
- “The quality is highly variable”
- Separate the questions from the specific technology
  - “Make sure input focuses on outcomes of importance to the patient rather than be specific to a given drug”
- 6/7 agreed patient preference ranking and 5/7 agreed targeted question based on specific disease/drug would be conducive to gathering valuable and objective patient information
- Should have sections for individual examples, as well as group summary
- Would like to add questions that address the broader impact of drug on patients’ and caregivers’ lives
- Most supported various forms of in-person discussion such as presentation, focus groups, and direct conversations with CADTH and patient/public members on CEDAC
- Respondents commented CADTH could consider more diverse form/media of submission

Source: CADTH Survey, interviews with subject matter experts and stakeholders, SECOR Analysis
Patients are satisfied with the guidance document and viewed training sessions to be helpful. CDR reviewers and CEDAC members noted more support could be provided to lay members.

**Quality Control**
- “Training sessions are helpful”
- Majority respondents are satisfied with guidance document

**Communication/SUPPORT MECHANISMS**
- Respondents have informed patient groups of the submission; however, they have a different approach to support other aspects of the process
  - “We’ve been trying to inform patient groups of this opportunity and to give them some insights (where we can) re the process…”
  - “Other than making a patient group aware of a CDR submission, we do not engage with patient groups in any way regarding the submission”

**Stated Opportunities for Improvement**
- Would like CADTH to give more support to lay representatives
- The guidance document could be more patient-friendly
  - “Could be more patient-friendly, including FAQs”
  - “Write from the patients’ perspectives; e.g., advice from patients to patients on how to prepare submissions”
- “Training on preparing submissions would provide value”
- “The challenge for the public members, of course, is that they don’t necessarily have the expertise to be critical of what they are receiving and presenting, and this impacts their ability to meaningfully participate in the discussion. One of them has actually observed this to me, incidentally”
- Would like to have an opportunity to comment on the draft summary before submitting to CEDAC
- Meeting with lay representatives would be helpful to ensure accurate information is presented
- Patient groups would like to have better understanding of information needed

**Disconnects in Opinion**
- Most groups feel they have adequate information about the drugs; however, no information is available for those who do not have adequate information
- 67% have a “fairly well” or “very well” understanding of the process

**Patient’s understanding of the technology under evaluation and the process**

<table>
<thead>
<tr>
<th></th>
<th>Patient</th>
<th>CEDAC members</th>
<th>Industry</th>
<th>CDR reviewers</th>
<th>Key informants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEDAC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Industry</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CDR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: CADTH Survey, interviews with subject matter experts and stakeholders, SECOR Analysis
Industry and patient respondents seek more clarity on how information is used in the decision-making process.

### Analysis: Survey Results — Outputs of Patient Input Process

#### Incorporation of Evidence

<table>
<thead>
<tr>
<th>Notable Strengths of Current Process</th>
<th>Disconnects in Opinion</th>
<th>Stated Opportunities for Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Most indicated using patient-important outcomes/issues identified in the submission contributed to protocol development and contextualizing clinical and economic data</td>
<td>▪ Half do not feel the information is useful for contextualizing clinical data</td>
<td>▪ Most say patient submissions have little influence on their final voting decision</td>
</tr>
<tr>
<td>▪ Most indicated using patient-important outcomes/issues identified in the submission contributed to protocol development</td>
<td></td>
<td>▪ 4/7 felt that inclusion of patient input information throughout the body of CDR reports does not contribute to CDR review</td>
</tr>
</tbody>
</table>

#### Transparency of Decision-Making

<table>
<thead>
<tr>
<th></th>
<th>10/14 have adequate understanding of CDR patient input process</th>
<th>67% have a “fairly well” or “very well” understanding of the process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large proportion identified that lack of understanding of patient input’s impact is a key gap, and would like to see CADTH demonstrate more accountability for the use of patient input</td>
<td></td>
<td>Would like more information on how the submission is being used in the process</td>
</tr>
<tr>
<td></td>
<td></td>
<td>○ “The perception among organizations is that our submissions are all but DISMISSED by some reviewers if they see any pharmaceutical funding whatsoever...this is incredibly unfair to the work we do”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ “Would like to see patient submissions transparent (e.g., posted online)”</td>
</tr>
<tr>
<td></td>
<td></td>
<td>▪ Would like clearer disclaimer on how the “conflict of interest” is used</td>
</tr>
</tbody>
</table>

Source: CADTH Survey, interviews with subject matter experts and stakeholders, SECOR Analysis
Context and methodology

Analysis

• Current state analysis of CDR patient input process
• CDR stakeholder — survey data analysis
• Comparative analysis — local and international peers

Assessment

Recommendations
Analysis: CADTH was Compared to 3 International HTA Agencies and 4 Canadian HTA Agencies
### Analysis: Summary Agencies Map Spectrum of Models

<table>
<thead>
<tr>
<th>Philosophy and Goal</th>
<th>New and Evolving</th>
<th>Range of HTA Agency Patient Input Models</th>
<th>Mature, Highly Resourced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Importance to decision-making</td>
<td>Minor consideration</td>
<td></td>
<td>Equal weighting with other evidence</td>
</tr>
<tr>
<td>Design</td>
<td>One stage</td>
<td></td>
<td>Multiple stages</td>
</tr>
<tr>
<td>Stage of incorporation</td>
<td>Limited, one-dimensional</td>
<td></td>
<td>Broad, varied</td>
</tr>
<tr>
<td>Mechanisms of solicitation</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Process**

- **Flexibility of input**<br>Limiting
- **Time allotment**<br>Conflict with review timeline
- **Utility**<br>Manual, complex

**Inputs**

- **Breadth of data points**<br>0<br>&gt; 5
- **Type/quality of data gathered**<br>Generic<br>Relevant
- **Quality control**<br>Minimal<br>Multi-faceted

**Outputs**

- **Incorporation of evidence**<br>Anecdotal<br>Systematic, proactive
- **Transparency of decision-making**<br>Transparency of decision-making<br>Timely, detailed, active

Note: Based on initial data-gathering from secondary sources, as well as limited interviews with select organizations; only where sufficient data was available to assess.
### Analysis: Overview of Agencies Compared to CADTH (I)

CADTH is among few HTA agencies that consider patient input as a piece of evidence

<table>
<thead>
<tr>
<th>Agency</th>
<th>Canada</th>
<th>United Kingdom</th>
<th>Scotland</th>
<th>Australia</th>
<th>Quebec</th>
<th>Ontario</th>
<th>BC</th>
<th>Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td>Philosophy and Goal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Launched in 2010</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Systematically incorporate input throughout the process”</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“We endeavour to treat patient input as an equal evidence as clinical and cost-effectiveness data”</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Launched in 2003</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Patient/carer perspective is taken into consideration by the SMC”</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Launched in ~2007</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Support HTA agencies to make decisions that will work for patients and clinicians”</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2007 (allow patient groups/individuals to intervene)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(public representatives)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“The data are definitely used”</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Launched in 2010</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Formal framework to systematically incorporate patient evidence into the drug review and funding process”</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Launched in 2007</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(public representatives)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“The data are definitely used”</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Launched in 2010</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“Patient is regarded on the same level as manufacturers as a relevant and impacted stakeholder. Goal is to have patient groups have more access to review information and be more active participants in review process”</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Design — Stage of incorporation

**Drug**
- Use submission for protocol development, integrated in the CDR review reports, and presented at the CEDAC discussion
- Submit ideas for topic selection, comment on scoping document and draft guidance, presented at appraisal discussion, may choose to appeal
- Overarching issues, drug and non-drug appraisals, and other work programs (clinical guidelines, etc.)
- Drugs submitted to decision making discussion
- Drugs
  - Consumer could submit comments on PBAC agenda
  - Presented at decision-making discussion
- Drugs
  - During the appraisal process (can ask for a meeting with the evaluation committee)
  - Presented at decision-making discussion
- Drugs
  - Summarized by patient member and presented to the committee during funding deliberation stage
- Drugs
  - Presented by public members during funding deliberation stage
- Drugs
  - Used for protocol development, the draft report, and decision-making discussion

**Patient group**
- Written submissions
- 2 public members on CEDAC (present submission information)
- 3 public members on PBAC (overarching ethical principles)
- The Patient and Public Involvement Group (PAPIG, provide overarching recommendations)
- Public members (present submission information)
- Patient group written submissions
- 1 patient representative on the committee speaks to the submission information (does not present the information)
- Patient group/individual patient written submissions (filtered by internal staff member)
- Consumer impact statements — produced by Consumer Health Forum at the request of PBAC secretariat to inform decision-making
- Patient group intervention
  - Remarks and suggestions from the public/patient
  - Public representative on standing committee
- Patient group written submission
  - 2 patient representatives on the committee
  - (present submission information)
- Patient group/individual patient and caregiver submission
  - 3 public members on the Council (present submission information)
- Patient representation on pCODR Expert Review Committee
- Patient written submission
  - Comments on the draft recommendation

**Source:** Agency websites, public documents, limited interviews with select organizations
## Analysis: Overview of Agencies Compared to CADTH (II)

<table>
<thead>
<tr>
<th>Agency</th>
<th>Canada</th>
<th>United Kingdom</th>
<th>Scotland</th>
<th>Australia</th>
<th>Quebec</th>
<th>Ontario</th>
<th>BC</th>
<th>Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process — Flexibility of input</strong></td>
<td>Patient groups can submit information up to 6 pages</td>
<td>No limit on number of pages (summary requested if &gt; 10)</td>
<td>No limit on number of pages</td>
<td>200 words for each answer</td>
<td>N/A</td>
<td>2-page limit (do provide flexibility if required)</td>
<td>No limit on length of answers</td>
<td>8-page limit</td>
</tr>
<tr>
<td><strong>Process — Time allotment (entire review process)</strong></td>
<td>Up to 25 business days with advance notice (if provided by manufacturer) 15 business days without advance notice (CDR process is ~6 months)</td>
<td>8 weeks for single technology appraisal and 14 weeks for multiple technology appraisal (appraisal process is ~1 year)</td>
<td>Up to 2 months (appraisal process is ~4.5 months)</td>
<td>14 business days (appraisal process 17 weeks)</td>
<td>N/A</td>
<td>1-3 months, shorter timeline if the drug is undergoing a “rapid review” (Timeline information not readily available for normal review, rapid review is 30 days)</td>
<td>4 weeks (Target timeline for standard review is 9 months; for complex review, 12 months)</td>
<td>Up to 1 month advance notice (if provided by submitter) plus 10 business days 10 business days without advance notice (Review process is 5-8 months)</td>
</tr>
<tr>
<td><strong>Process — Utility</strong></td>
<td>A section on web page dedicated for patient input; the review process posted on website; the submission document to be completed and submitted online or faxed</td>
<td>A section on web page dedicated for patient involvement; each topic has web page; review process, and large amount of education material is made available</td>
<td>A section on web page dedicated for patient input</td>
<td>Little information on patient engagement; no process map posted; patient submission can be submitted online</td>
<td>No dedicated section for patient input in English on website</td>
<td>A section on webpage dedicated for patient input; the review process posted on website; the submission document to be completed and submitted via email/fax/mail</td>
<td>A section on web page dedicated for patient input; the review process is posted on website; input is entered on a submission form, which can be submitted online or emailed</td>
<td></td>
</tr>
</tbody>
</table>

*Source: Agency websites, public documents, limited interviews with select organizations*
## Analysis: Overview of Agencies Compared to CADTH (III)

<table>
<thead>
<tr>
<th>Agency Name</th>
<th>Canada</th>
<th>United Kingdom</th>
<th>Scotland</th>
<th>Australia</th>
<th>Quebec</th>
<th>Ontario</th>
<th>BC</th>
<th>Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inputs: Breadth of data points</strong></td>
<td>Range from 0 to 9 per submission, with average of 1.8 submissions and median of 1 submission</td>
<td>“A couple, sometimes 3 or 4”</td>
<td>Information not readily available</td>
<td>“Major submissions (0 to a couple), less for minor submissions”</td>
<td>N/A</td>
<td>April 2010 to June 2011, average of 0.63 submission/review</td>
<td>Average 16 submissions/drug. For the 16, 8.8 from individual patients, 5.5 from caregivers, and 1.7 from patient groups</td>
<td>Information not readily available</td>
</tr>
<tr>
<td><strong>Inputs: Type/quality of data gathered</strong></td>
<td>“The quality is variable”</td>
<td>Generic questions on submission form</td>
<td>Generic questions on submission form</td>
<td>Generic questions on submission form</td>
<td>N/A</td>
<td>Generic questions on submission form</td>
<td>Generic questions on submission form</td>
<td>“The quality is variable”</td>
</tr>
<tr>
<td><strong>Inputs: Quality control</strong></td>
<td>Has organized 1 training session</td>
<td>Has organized a training day in 2011</td>
<td>Sample patient input posted online</td>
<td>No formal feedback</td>
<td>N/A</td>
<td>A review was completed 12 months after input was solicited from general public from manufacturers, DBC members, and ministry staff</td>
<td>Guidance document ~Quarterly webinars</td>
<td>Guidance document No formal feedback</td>
</tr>
<tr>
<td><strong>Outputs: Incorporation of evidence</strong></td>
<td>Input is considered at each designated stage</td>
<td>Input is considered at each designated stage</td>
<td>Input is considered at decision-making stage (presented by one of three public members after clinical and cost-effectiveness evidence)</td>
<td>Input is considered when patient groups intervene</td>
<td>Input considered at funding deliberation stage</td>
<td>No information on how evidence is incorporated</td>
<td>Patient input incorporated into clinical and economic reports A deliberative framework is used to form recommendation</td>
<td></td>
</tr>
<tr>
<td><strong>Outputs: Transparency of decision-making</strong></td>
<td>A section that includes summaries of patient input information in final recommendation, no specifics about how information is used</td>
<td>Section in draft guidance consultation document sets out each input. No detailed specifics about how information was used</td>
<td>PBAC produces a public summary document of decisions and reasons</td>
<td>Patient groups participate in the intervention meetings</td>
<td>Committee discussions relating to patient input summarized in &quot;transparency bulletins&quot; outlining committee recommendation and its rationale</td>
<td>No public information about how information impacted the decision-making</td>
<td>Patient group submission is integrated into various parts of the report (clinical report) (posted online) Patient feedback on recommendation is posted online</td>
<td></td>
</tr>
</tbody>
</table>

Source: Agency websites, public documents, limited interviews with select organizations
Analysis: Key Findings From Comparative Analysis (I)

**Relevant findings from comparative analysis**

**Importance to decision-making**
- NICE — Endeavours to have patient input as “an equal leg of the evidence stool,” along with clinical and cost-effectiveness evidence
- NICE — Patient group presentations required to state conflicts up front
- pCODR – Patients, as a relevant and impacted stakeholder group, are regarded on the same level as manufacturers
- pCODR — Only allows patient groups who receive funding from more than one funder; no single funder provides more than 50% of the group's operating funds to submit evidence; COI of patient group also posted online

**Stage of incorporation**
- NICE & PBAC — Incorporate patient input for all topics (including non-drug and clinical guidelines)
- NICE — Incorporates patient input at every stage of drug appraisal process in different forms; patient groups can appeal on certain grounds
- pCODR — Allows patient groups to comment on draft recommendations

**Design**
- NICE — Standing lay committee members present at committee meetings, patient experts attend and answer questions
- PBAC — Patient representatives are well connected within the patient community and have a strong voice at the decision-making table
- PBAC, BC, Quebec — Accept individual patient input
- NICE — Only accepts input from national patient organizations (but anyone may comment on draft guidance via the website)
- PCODR — Individual patients not allowed to submit input but can contact pCODR if there is no patient advocacy group for a particular cancer type
- Denmark HTA agencies conduct their own systematic literature research on patient information

*Source: Agency websites, public documents, limited interviews with select organizations*
### Relevant findings from comparative analysis

<table>
<thead>
<tr>
<th>Execution</th>
<th>Process</th>
<th>Inputs</th>
<th>Outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flexibility of input</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• NICE — No limit on number of pages for patient groups, but asks patient groups to present a 1-page summary if submission is &gt; 10 pages</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Time allotment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Timeline allotment varies by agency depending on the overall review process</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Utility</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• BC formulary — Allows patients/caregivers/patient groups to fill out the submission form directly online</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Breadth of data points</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• BC formulary — Had higher number of data points than other HTA agencies because it accepts submissions from individual patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Type/quality of data gathered</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• BC formulary — BC had disease-/drug-specific questions previously but only generic questions now</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• SMC — Recently updated its submission form based on the feedback from Public Involvement Officer who supports patient groups to make submissions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Quality control</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• SMC — Has posted a sample patient submission online, supports a part-time Public Involvement Officer who gives advice/feedback to patient groups on submissions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• NICE — Sophisticated Patient and Public Involvement Programme, support patient groups and lay representatives through various informal (e.g., email, telephone) and formal formats (e.g., training sessions)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Incorporation of evidence</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• pCODR — Has established a deliberate framework to incorporate patient input</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• NICE — Reviewers receive patient input data verbatim</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• NICE — One of the initiatives this year is to improve the &quot;methods guide&quot; for reviewers/committee members, including the section on patient input data integration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Transparency of decision-making</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• NICE — Sends draft guidance verbatim to patient groups</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• NICE — Provides resource support (e.g., a meeting room) to Patients Involved in NICE, an independent forum that exists to provide organizations who engage with NICE with a system of mutual support and information-sharing, and to act as a &quot;critical friend&quot; to NICE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• PBAC — Recuperates its review cost by charging industry members by submission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Australia — Consumer Health Forum (not supported by PBAC) occasionally provides support to patient groups</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Source: Agency websites, public documents, limited interviews with select organizations*
Contents

Context and methodology

Analysis

• Current state analysis of CDR patient input process
• CDR stakeholder — survey data analysis
• Comparative analysis — local and international peers

Assessment

Recommendations
# Assessment: Initial Mapping of CADTH Relative to Peers

## Philosophy and Goal
- **Importance to decision-making**: Minor consideration
- **Design**: One stage
- **Mechanisms of solicitation**: Limited, one-dimensional

## Process
- **Flexibility of input**: Limiting
- **Time allotment**: Conflict with review timeline
- **Utility**: Manual, complex

## Inputs
- **Breadth of data points**: 0
- **Type/quality of data gathered**: Generic
- **Quality control**: Minimal

## Outputs
- **Incorporation of evidence**: Anecdotal
- **Transparency of decision-making**: Transparency of decision-making

## Range of HTA Agency Patient Input Models

<table>
<thead>
<tr>
<th>Philosophy and Goal</th>
<th>New and Evolving</th>
<th>Range of HTA Agency Patient Input Models</th>
<th>Mature, Highly Resourced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Importance to decision-making</td>
<td>Minor consideration</td>
<td>CADTH</td>
<td>Equal weighting with other evidence</td>
</tr>
<tr>
<td>Stage of incorporation</td>
<td>One stage</td>
<td>CADTH</td>
<td>Multiple stages</td>
</tr>
<tr>
<td>Mechanisms of solicitation</td>
<td>Limited, one-dimensional</td>
<td>CADTH</td>
<td>Broad, varied</td>
</tr>
<tr>
<td>Flexibility of input</td>
<td>Limiting</td>
<td>CADTH</td>
<td>Adaptable to given context</td>
</tr>
<tr>
<td>Time allotment</td>
<td>Conflict with review timeline</td>
<td>CADTH</td>
<td>In line with review timeline</td>
</tr>
<tr>
<td>Utility</td>
<td>Manual, complex</td>
<td>CADTH</td>
<td>Automated, user-friendly</td>
</tr>
<tr>
<td>Breadth of data points</td>
<td>0</td>
<td>CADTH</td>
<td>&gt; 5</td>
</tr>
<tr>
<td>Type/quality of data gathered</td>
<td>Generic</td>
<td>CADTH</td>
<td>Relevant</td>
</tr>
<tr>
<td>Quality control</td>
<td>Minimal</td>
<td>CADTH</td>
<td>Multi-faceted</td>
</tr>
<tr>
<td>Incorporation of evidence</td>
<td>Anecdotal</td>
<td>CADTH</td>
<td>Systematic, proactive</td>
</tr>
<tr>
<td>Transparency of decision-making</td>
<td>Transparency of decision-making</td>
<td>CADTH</td>
<td>Timely, detailed, active</td>
</tr>
</tbody>
</table>

---

**Scottish Medicines Consortium**

---

Scottish Medicines Consortium
Assessment: CADTH Assessment — Philosophy/Goal and Design

**Importance to decision-making**

- **CADTH** — Patient input is not given the same weighting as clinical and cost-effectiveness data due to perceived lack of objectivity of the data sensed by CEDAC members and CDR reviewers
  - Most CDR reviewers and CEDAC members feel the information collected is relevant for CDR; however, not all are comfortable with using information for decision-making due to perceived conflicts/lack of objectivity/lack of representation
  - Industry respondents do not believe that patient input has enhanced CDR
- At NICE, patient evidence is given equal weighting with clinical and cost-effectiveness evidence

**Stage of incorporation**

- **CADTH** — Patient input is collected at the beginning of the process and is designed to be used for protocol development, incorporated in the CDR review reports, and presented by lay representatives
- Patient groups are not consulted at the draft report stage and reconsideration stage (this may be constrained by factors such as confidentiality agreement); comparatively, agencies such as NICE and pCODR allow patients to comment on draft reports, with valid grounds (patient groups can also ask for an appeal at NICE or a procedural review at pCODR)
- A few other agencies incorporate input at select stages only — PBAC and SMC do not consider patient input at the protocol stage, SMC considers patient evidence at the committee discussion
- CDR reviewers and CEDAC members believe that patient information has contributed to various stages of the CDR review

**Mechanisms of solicitation**

- Patient input currently received via written submissions to CADTH via patient groups; patient input is presented by public members at the CEDAC deliberations
- Most CDR reviewers, CEDAC members, and patient groups agree that other stakeholders such as individual patients/caregivers/professionals could provide input; however, there is no clear inclination toward any particular group(s)
- Comparatively, PBAC and NICE have patient experts present at committee meetings; NICE and pCODR also allow patient groups to make comments on draft reports (with valid grounds, patient groups can also ask for appeal at NICE or a procedural review at pCODR)

*Source: SECOR Analysis*
Assessment: CADTH Assessment — Patient Submission Process

- Most patient groups felt the CADTH submission template allowed patient groups to describe the issues/outcomes that are important to the group, although some expressed that the submission form is not long enough.
- Comparatively, NICE, SMC, and BC do not have a limit on the length of the submissions, while organizations such as PBAC, Ontario, and pCODR have more stringent limits.

Utility

- There is a website page dedicated to patient submission; a guidance document and the CDR process is posted on website; patients can make submissions online or via fax; and contact information is available should patient groups have any questions.
- Most groups are “fairly” or “very satisfied” with the accessibility of the website and the submission form.
- Some noted opportunities for improvement:
  - Better navigation structure of the website
  - CADTH could send disease-specific e-alerts
  - CADTH sends “Calls for Patient Input” emails to notify patient groups; PBAC only pastes the information on its website; NICE actively searches the database for relevant patient groups and invites them to participate in a targeted way (i.e., not all groups in the database are alerted for every review).

Time Allotment

- Current patient input process respects the existing CDR timelines.
- However, a large proportion of patient groups indicated that they do not have enough time to complete submission; the CDR reviewers have also commented that perhaps more time is needed for patient groups.
- Industry members have suggested that it is possible to provide more advance notice to the patient groups.
- While NICE's time allotment is significantly longer, its appraisal process is approximately 1 year; SMC, while giving patient groups up to 2 months, does not consider the patient information until the decision-making stage.

Source: SECOR Analysis
**Assessment: CADTH Assessment — Data Inputs**

**Breadth of data points**
- Number of patient submissions range from 0 to 9 per review, with average of 1.8 submissions and median of 1 submission; CADTH does not accept individual patient input
- From the 8 HTA agencies examined, BC, Quebec, and PBAC are the only ones that accept individual patient submissions;
- CADTH’s number of data points is in line with most HTA agencies that accept patient group submissions; the number varies depending on the drug under review
- BC and Quebec have higher data points mainly due to the acceptance of individual patient and caregiver input

**Type/quality of data gathered**
- Most CDR reviewers and CEDAC members feel the information is valuable, not otherwise obtainable. More CDR reviewers and CEDAC members feel the requested information elicits the most relevant patient values
- CDR reviewers commented the quality of submissions is highly variable, which is a comparable situation with a few other agencies such as pCODR and PBAC
- Most CDR reviewers, CEDAC members, and patient groups agree that other stakeholders such as individual patients/caregivers/professionals could make inputs; however, there is no clear inclination toward any particular group(s) nor type of data (e.g., survey), and 6/7 CEDAC members agreed patient preference ranking would be helpful to gather valuable and objective patient information
- Most HTAs have generic questions (not disease-specific) on submission forms
- Most patient groups agree that they welcome some form of in-person discussion (focus groups, presentation, etc.)

**Quality control**
- A guidance document is available on CADTH website; CADTH has organized one patient group training session in 2011
- Patients support more training sessions and better support mechanisms, and would like an opportunity to comment on the draft summary before submitting to CEDAC discussion; industry groups has commented that more support from CADTH is needed
- CDR reviewers and CEDAC members have commented that providing training for lay members would be valuable
- SMC has dedicated resources to support patient groups in making submissions; NICE has organized multiple training sessions for lay members and has full-time staff dedicated to all patient initiatives in drug appraisal; SMC has also posted sample submission documents on website

Source: SECOR Analysis
Incorporation of evidence

- Most CDR reviewers and CEDAC members indicated patient-important outcomes/issues have contributed to protocol development; CDR reviewers also noted patient information is useful for contextualizing clinical and economic data.
- However, most CEDAC members say patient submissions have little influence on their final voting decisions.
- While most agencies do not have a systematic framework to incorporate patient data, comparatively pCODR has published a "deliberative process" framework for patient evidence incorporation.

Transparency of decision-making

- Patient groups and industry have a fairly good understanding of the patient input process.
- There is a section in the final recommendation that summarizes the patient input information; however, patient groups and industry are unclear about how patient information is used during decision-making.
- Most HTA agencies do not have public information about how patient information impacted decision-making; NICE, which is the most transparent agency, sends draft guidance verbatim to patient groups.

Source: SECOR Analysis
Context and methodology

Analysis

• Current state analysis of CDR patient input process
• CDR stakeholder — survey data analysis
• Comparative analysis — local and international peers

Assessment

Recommendations
Recommendations: Philosophy and Goals

Strategic

G1 Clearly define the objective of patient input and align internal and external stakeholders, accordingly

G2 Increase transparency by communicating how patient information is used in decision-making process — during and after the review is published

G3 Further increase awareness of program among patient groups, and broader patient community in order to broaden reach of intake

For further consideration

G4 Reduce duplication of patient input process in BC and Ontario and continue to forward the patient input information to jurisdictions
Recommendations: Design

**Strategic**

- **D1** Establish a framework to more objectively and systematically incorporate patient input into the decision-making process.

- **D2** Establish strategic relationships with research agencies such as CFHI and academia to diversify sources of patient-based evidence.

- **D3** Create opportunities for individual patients/caregivers to be engaged in the process without necessarily accepting individual patient submissions (e.g., have patient experts at decision-making table, provide links to patient groups should an individual patient want to make a submission, post patient preference-ranking of outcomes of importance online).

**Tactical**

- **D4** Continue to share and exchange patient group email lists with Ontario and BC, include patient groups currently not subscribed to the mailing list.

**For further consideration**

- **D5** Sign a non-disclosure agreement with manufacturers so draft report can be released to public for comments.
Recommendations: Submission Process

**Strategic**

- **P1** Encourage industry to give even more advanced notice to CADTH, when possible

**Tactical**

- **P2** Increase flexibility of input by removing or increasing the page limit; ask patient groups to submit a summary if the information is > 10 pages
- **P3** Send disease-specific alerts
- **P4** Send patient group an email receipt when submission has been received
Recommendations: Data Inputs

**Strategic**

I1 Schedule periodic formal communication opportunities with patient groups to understand needs and incorporate feedback into improvements for the overall process.

I2 Devote a half-time/full-time employee to patient engagement initiatives to support patient groups on making submissions (e.g., provide advice and feedback to patient groups).

**Tactical**

I3 Demonstrate what a “good” submission is by posting examples online.

I4 Allow patient groups to review draft summary of patient input before CDEC discussion.

I5 Organize and deliver quarterly training sessions to public members on CDEC committee.

I5 Organize and deliver quarterly training sessions to patient groups.
Recommendations: Outputs

Strategic

O1 Establish a framework to systematically and objectively incorporate patient input as an evidence for decision-making (same as D1 in slide #35)

O2 Increase transparency by communicating how patient information is used in decision-making process; e.g., distribute verbatim comments, explicitly summarize how data contributed to decision-making (same as G3 in slide #34)

Tactical
Recommendations: Vision for Future Patient Input Initiative

Stakeholder alignment and engagement
- Internal and external stakeholders aligned on the objectives of patient input process (G1, slide #34)
- Increased awareness of patient input initiative among patient groups and broader patient community (G3, slide #34)
- Strategic relationship established with research agencies such as CFHI and academia, broader source of patient information is considered (D2, slide #35)
- Periodic formal communication opportunities exist for patient groups to give feedback (I1, slide #37)

Incorporation of evidence
- A framework established to incorporate patient input objectively and systematically (D1, slide #35; O1, slide #38)
- Opportunities available for individual patients engaged in the process (D3, slide #35)

Education
- A full-time/half-time employee available to support groups on making submissions (I2, slide #37)
- Quarterly training sessions for patient groups and public members on CEDAC (I5, I6, slides #37)

Written Submission Process

- Receipt of drug submission
- Reviewer report developed by review team
- CEDAC Brief (reviewer report, manufacturer’s comments, patient input)
- Initial CEDAC Recommendation (sent to drug plans, FWG, and manufacturers)
- Embargo period
- Reconsideration/Resubmission based on reduced price
- Final CEDAC Recommendation

Patient input
- Patient groups can review draft summary of patient input (I4, slide #37)
- Individual patient experts on the committee (D3, slide #35)

Groups subscribe to “Calls for Patient Input” email service
- “Calls for Patient Input” released upon CDR submission
- Patient groups make a submission
- CADTH sends patient group an email receipt (P4, slide #36)
- Examples of “good” submissions posted online

CADTH shares and exchanges patient group email lists with BC and Ontario
- CADTH sends disease-specific alerts (P4, slide #36)
- Links and contact information of patient groups available on website for individual patients (D3, slide #35)
- No page limit on submission forms (P2, slide #36)

Industry is encouraged to give even more advanced notice to CADTH when possible (P1, slide #36)

Up to 25 business days (with advance notification) or 15 business days (regular process)

Final recommendation include details on how patient information impacted decision-making or verbatim send to participating patient groups (G2, O2, slides #34 and #38)

Examples of “good” submissions posted online

No page limit on submission forms

Current patient input process

Changes to future process

CADTH

SECOR