In the balance:
A Renewed Vision for the Common Drug Review

April 2012
Executive Summary

Purpose of This Report: A New Vision

Equal and timely access to medications as clinically appropriate is an important issue for people with chronic diseases, given the link between these supports and optimal self-management of their disease. A study of the Common Drug Review (CDR) by the House of Commons concluded that while it had provided a good start toward harmonizing the drug review process in Canada, further improvements were necessary. In the Balance: A Renewed Vision for the Common Drug Review has been drafted in this spirit, to provide an enhanced vision for the drug review process in Canada.

Why We Are Here

Why the Common Drug Review is important

• Half of all Canadians have a chronic condition. This includes diabetes and related complications.
• Almost one-quarter of Canadians with a chronic condition don’t take their prescribed medications because they can’t afford them. When it comes to diabetes, over half of those with the disease don’t comply, increasing their risk for complications.
• The CDR is an integral part of the drug review process. Millions of Canadians are affected by CDR recommendations on formulary listings.
• While the CDR has resulted in improvements in the drug review process, challenges remain, including:
  o Continued duplication in the review process.
  o Lack of agreement between CDR recommendations and drug plan decisions.
  o Differences in length of time to reach decisions.
  o Concerns over the appeals process.
  o The balance of evidence between efficacy, cost-effectiveness and patient experience.
• Continuing challenges with the CDR mean lack of access to medications for Canadians. There is evidence that Canada's public drug plan reimbursement lags behind other OECD countries for chronic diseases and conditions. For diabetes drugs, access is unequal across participating drug plans.

What Can Be Done

How the Common Drug Review can be enhanced

1) Examine national and international best practices to address challenges in the drug approval process to:

  • Eliminate duplication in the drug review process. Work with participating drug plans to minimize duplication of effort and differences in coverage decisions by enhancing the review process and implementation of decisions.
  • Introduce greater transparency in the public engagement and review process. Implement practices to standardize and ensure quality in the review process, such as optimizing committee review representation and improving the appeals process.
  • Reduce the timelines of the drug review process. Work with participating drug plans to consider ways to standardize times for making decisions and reduce disparities in access.
  • Improve the balance of the criteria used to make drug funding decisions. Ensure the appropriate balance between cost-effectiveness, clinical effectiveness and patient experience through enhanced public engagement mechanisms.

2) Have federal, provincial and territorial governments collaborate to enhance pharmacare coverage in Canada, as committed to under previous health accords. This includes catastrophic drug coverage and a pan-Canadian drug formulary.
Key Areas of Investigation and Key Questions

1) Governance and decision-making to streamline the drug review process and enhance patient input.
   • Has the CDR reduced overlap and duplication in the drug review process in Canada?
   • Has the CDR increased the standardization and quality of drug reviews across Canada?
   • Does the CDR have appropriate appeals processes in place for its recommendations?

2) Review of timelines to provide more timely access to more efficient drugs, as clinically appropriate.
   • Has the CDR led to more timely and improved access to newer, more efficient drugs, as clinically appropriate?
   • Has the number of drugs covered by public drug plans increased or decreased since the CDR was introduced?

3) Balance of evidence between efficacy, cost-effectiveness and patient experience.
   • Has the CDR contributed to more transparent and evidence-based decision-making?
   • Is there an appropriate balance of information used in the CDR?
   • Are mechanisms sufficient to enable patients and other stakeholders to provide evidence?
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Finally, we thank you for taking the time to read this report, and we welcome your feedback at advocacy@diabetes.ca

Note: The opinions expressed in this document are the views of the Canadian Diabetes Association and do not necessarily reflect those of the Project Advisory Committee, key informants or the researchers and consultants for the report.
Informing Methodology

The findings and discussion in this report are supported by multiple lines of evidence, as follows.

- **Project Advisory Committee:** This research study was guided by a Project Advisory Committee composed of diabetes educators, physicians and other healthcare providers, researchers, health non-governmental organizations, healthcare advocates, industry, arm’s-length government agencies and other Common Drug Review (CDR) stakeholders, with expertise in health/pharmaceutical policy, drug review processes and/or formulary decision-making. The Project Advisory Committee provided advice concerning the development of the project.

- **Literature Review:** An environmental scan/literature review of resources, reports and studies pertaining to centralized or common drug review processes was first undertaken to document the evolution of the CDR in Canada. For comparison purposes, this review was supplemented by a search of published, peer-reviewed and grey-literature reports and studies describing centralized drug review processes in a variety of international jurisdictions.

- **Jurisdictional Review:** The review looked at international jurisdictions to assess how Canada compares internationally and explore best practices to inform the continued evolution of the CDR in Canada. A high-level review of 10 jurisdictions was initially conducted (including Canada), with a more detailed review of four jurisdictions: the United Kingdom (UK), Australia, New Zealand and Sweden. Background information was obtained on each of the four selected centralized drug review processes by searching government publications/websites, supplemented as needed by academic literature.

- **Stakeholder Survey:** A short online survey was undertaken with key stakeholders to identify positive outcomes of the CDR; whether it has met stakeholder expectations; concerns and suggestions for improvement; and particular areas where the Canadian Diabetes Association should focus its research in relation to the CDR. Key stakeholders included government, regulators, industry/manufacturers, healthcare providers, academics, not-for-profit/community-based organizations, people with diabetes and other individuals with a vested interest in this project. In total, 25 key stakeholders (out of 52) responded to the survey. Information provided as part of this survey was integrated with other results and presented in a summary format, using the identifier “Stakeholder Pulse” throughout the report.

Glossary of Terms

- CDR  Common Drug Review
- CADTH  Canadian Agency for Drugs and Technologies in Health
- CDEC  Canadian Drug Expert Committee
- CEDAC  Canadian Expert Drug Advisory Committee
- CMAJ  Canadian Medical Association Journal
- F/P/T  federal/provincial/territorial
- HESA  House of Commons Standing Committee on Health
- NICE  National Institute for Clinical Excellence (United Kingdom)
- OECD  Organisation for Economic Co-operation and Development
Section I: Introduction

What Is the Common Drug Review?

In an effort to standardize processes and enhance the consistency, quality and efficiency of drug reviews, Canada’s health ministers in 2002 tasked the Canadian Agency for Drugs and Technologies in Health (CADTH)\(^1\) to establish a national Common Drug Review. The CDR was established in September 2003 in an attempt to consolidate nearly 18 drug review processes into a collaborative pan-Canadian federal/provincial/territorial (F/P/T) process (with the exception of Quebec). The CDR is an important component of the drug review continuum in Canada, following Health Canada’s review for safety and efficacy and preceding participating drug plan formulary decisions.

Unlike coverage for hospitals and physician services, public drug coverage is not guaranteed in Canada. Enhanced pharmacare was part of the National Forum on Health (1997)\(^2\) and F/P/T health accords, including catastrophic drug coverage (2003) and a national formulary (2004).\(^3,4\) Unfortunately, while some provinces have enhanced coverage for those on low incomes or with high drug costs, a national coordinated plan remains stalled.\(^5\) The result is “a jumbled assortment of public and private plans in which individual coverage is no longer based on patients’ needs, but subject to where people live and work, as well as on each person’s and family’s financial means.”\(^6,7\)

A CDR review is based on the following considerations: How does a drug compare with alternatives? Which patients will it benefit? Will it deliver value for money? While the CDR is an advisory body, participating drug plans will not consider listing drugs that have not been reviewed by the CDR. Nine to 10 million Canadians are affected by CDR recommendations.\(^8\)

The CDR has resulted in positive developments for the drug review process in Canada, including the following:

- **Transparency of the drug review process.** Prior to the implementation of the CDR, the reasons behind drug plan decisions for formulary listings were not publicly available.\(^9\) Prompted by requests for access to more information from drug plans, manufacturers and other key stakeholders, all interested parties can now monitor the status of drug submissions and review the rationale behind Canadian Drug Expert Committee (CDEC) recommendations on the CADTH website.

- **Length of time for reviews.** The median time-to-listing for all drugs (i.e. the time between submission to CDR, final recommendation and when the drug is listed by public drug plans) has decreased with the introduction of the CDR.\(^10\) The CDR has also introduced priority review submissions in response to stakeholder feedback calling for greater coordination between Health Canada and the CDR to facilitate earlier reviews and recommendations on priority drugs.

- **Public engagement and involvement.** In response to requests from patient groups, two members of the public were appointed in 2006 to the CDEC, which makes recommendations on behalf of the CDR. In 2010 the “patient group input” initiative was launched to provide formal input into the CDR process.
Why Is the Common Drug Review Important for Canadians?

Equal and timely access to medications is an important issue for the 16 million Canadians with a chronic condition, 11 including diabetes and related complications (i.e. cardiovascular disease, stroke, kidney failure, non-traumatic lower limb amputation, blindness and depression). This is because 90% of Canadians with these conditions take at least one prescription drug, and 54% take four or more. 12 Since pharmaceuticals are not covered by the Canada Health Act outside of those administered in hospitals, Canadians with chronic disease who do not fall under specific public coverage (e.g. social assistance, benefits to seniors, etc.) or private insurance through employers or other sources can have excessive out-of-pocket costs. These costs can be a significant barrier to compliance with prescribed drug therapy: while about 10% of Canadians overall skipped medications due to cost, 23% of those with a chronic disease did. 13 While one in 10 Canadians have difficulty paying for prescribed medications even if they have insurance coverage, this rises to one in four for those without coverage. Those with the most difficulty have chronic conditions with recurring drug costs. 14 These costs are particularly onerous for people with diabetes and related complications: most have catastrophic drug costs of more than $1,500, or 3% of individual annual income. As a result, over half do not comply with prescribed therapies, thus compromising their diabetes management and leaving them vulnerable to serious and costly complications. 15

A 2007 review of the CDR by the House of Commons Standing Committee on Health (HESA) concluded that the CDR was “a good start,” but the committee also strongly agreed with witnesses that “further improvements are necessary” to the drug review process. 16 This report was conceived in this spirit to launch a dialogue to advocate for further enhancement in the following areas, and key questions were identified to inform a renewed vision for the CDR within an optimized drug review process:

1) Governance and decision-making to streamline the drug review process and enhance patient input.
   • Has the CDR reduced overlap and duplication in the drug review process in Canada?
   • Has the CDR increased the standardization and quality of drug reviews across Canada?
   • Does the CDR have appropriate appeals processes in place for its recommendations?

2) Review timelines to provide more timely access to more efficient drugs, as clinically appropriate.
   • Has the CDR led to more timely and improved access to newer, more efficient drugs, as clinically appropriate?
   • Has the number of drugs covered by public drug plans increased or decreased since the CDR was introduced?

3) Balance of evidence between efficacy, cost-effectiveness and patient experience.
   • Has the CDR contributed to more transparent and evidence-based decision-making?
The balance between clinical efficacy, cost effectiveness and patient experience is especially important for those with chronic diseases, given the impact of access on adherence to prescribed therapy and, in turn, improved health outcomes.

In the Balance: A Renewed Vision for the Common Drug Review

• Is there an appropriate balance of information used in the CDR?
• Are mechanisms sufficient to enable patients and other stakeholders to provide evidence?

While the CDR has resulted in improvements to the drug approval process, challenges remain that continue to impact access to drugs that have been deemed safe and effective by Health Canada, including the following:

• **Continued duplication in the drug review process.** The CDR was introduced to reduce duplication in the drug review process and address differences in coverage among publicly funded drug plans. However, some participating drug plans continue to conduct their own reviews after CDR recommendations have been made, using the same criteria.

• **Lack of agreement between CDR recommendations and drug plan decisions.** While respecting provincial/territorial delivery for healthcare, the variation in agreement between formulary listings and CDR recommendations across participating drug plans points to a number of issues, such as 1) why individual jurisdictions still conduct their own reviews, and 2) the need for the CDR in the overall drug review process if participating drug plans are not bound by CDR recommendations. It has also led to disparities in formulary coverage and access to medications between jurisdictions.

• **Differences in length of time to reach decisions.** The CDR was introduced to provide more timely and improved access to newer and more efficient drugs as clinically appropriate, thus reducing variations in access for patients. However, the review process has remained relatively unchanged. While the median time-to-listing for drugs has decreased since the CDR was introduced, differences in review times persist across jurisdictions.

• **Concerns over the appeals process.** Patient advocacy groups, including the Canadian Diabetes Association, have raised concerns that appeal of a CDR recommendation is limited to the industry manufacturer who submitted the initial application for review. While recommendations and the reasoning behind them are posted on the CADTH website, there is no formal process for patients or patient organizations to ask questions about CDR recommendations. In addition, there are concerns that reviewers of appeals are the same as those who made the initial recommendations.

• **Balance of evidence.** While the CDR has introduced a mechanism to allow patient input, cost-effectiveness continues to be the primary consideration in determining recommendations. This is important, since the number of drugs covered by public drug plans has decreased since the introduction of the CDR. This raises questions about the balance of evidence between cost-effectiveness, clinical effectiveness and patient experience.

Spending on drugs grew by 4% to $32 billion between 2010 and 2011, or 16.2% of total healthcare spending. Of this total, 61% is private spending and 39% is public spending. We must be cognizant of the limited public dollars for healthcare, and the drug review process must include cost-effectiveness to ensure that limited resources are spent wisely. However, an appropriate balance between cost-effectiveness, clinical efficacy and patient experience must be achieved to ensure that access is not denied to medications that can improve the lives of Canadians.
Section II: Key Findings

Governance and Decision-Making

The aim of the CDR is to:

• Streamline the drug review process.
• Reduce duplication of the drug review process by jurisdictions.
• Increase the standardization and quality of drug reviews across Canada to maximize the use of limited resources.

Key Questions

• Has the CDR reduced overlap and duplication in the drug review process in Canada?
• Has the CDR increased the standardization and quality of drug reviews across Canada?
• Does the CDR have appropriate appeals processes in place for its recommendations?

Assessment of Current System

The CDR has a unique role in Canada’s drug review continuum. Once Health Canada approves a drug for sale based on efficacy, safety and quality (cost is not a consideration), it must be reviewed by the CDR to obtain coverage under Canada’s public drug plans (with the exception of Quebec).24 By design, the CDR is to conduct rigorous, objective and timely reviews of each drug’s clinical and cost-effectiveness in comparison to other available therapies. On the basis of the review, it then makes a recommendation regarding whether the drug should be funded by participating drug plans.25

As noted in CADTH’s 2011–2012 annual business plan, “The Common Drug Review program remains a flagship program for CADTH and will continue to evolve in direct support of F/P/T Drug Plans.”26 Publicly funded drug plans are not required to follow CDR recommendations, since they must also consider their jurisdiction’s own healthcare priorities, available resources and the precedence of previous formulary decisions.27 Given that the CDEC’s mandate is advisory, recommendations are not binding, nor do they play a role in or have an influence on the nature and timing of decisions.28 Final funding decisions are based on the following:

Stakeholder Pulse

CDR has resulted in “savings for some provinces that did not have an evaluation process previously and added transparency in the process which was not evident prior to the CDR.”

— Academic and researcher

“By providing an assessment of whether a new drug represents ‘value for money’ from a societal point of view, the CDR aims to help drug plans balance access to effective treatment with fairness and affordability across the health system.”

— CADTH, Submission Brief to House of Commons Standing Committee on Health, April 25, 2007

“... federal and provincial drug insurance plans told the Committee that ... In their view, the CDR process saves time, effort and money. It has reduced duplication of effort across the provincial, territorial and federal drug plans and has allowed all jurisdictions—large and small—to have equal access to a high level of evidence and expert advice from the CDR.”

• CDR recommendations
• advice from the drug plan’s own expert advisory committee
• patient and societal impact
• public interest
• product listing agreements with manufacturers
• drug program budgets
• government priorities.

A more detailed summary of the CDR process is provided at: http://cadth.ca/products/cdr/cdr-overview.

**Continuing Challenges**

1. Overlap/Duplication

One of the main intents of establishing the CDR was to reduce duplication in the drug review process and address differences in drug coverage among publicly funded drug plans. The CDR was positioned as a national formulary—a building block for the national pharmaceutical strategy urged by the 1997 National Forum on Health, and the 2004 National Pharmaceuticals Strategy. Once implemented, participating drug plans were to dismantle their individual drug review processes concerning safety, efficacy and cost-effectiveness, and focus their review on budgetary impacts in relation to the health priorities for their province or territory.

While provinces indicate that they do not duplicate the work of the CDR but instead consider CDR recommendations in light of their own priorities, needs and resources, some continue to conduct their own reviews with similar criteria. For example, Ontario's Committee to Evaluate Drugs is mandated to “evaluate the clinical value of drug products, interchangeability of generic drug products and cost-effectiveness of drugs and makes recommendations ... regarding coverage of these products through Ontario Public Drug Programs and the New Drug Funding Program for cancer care.” This can delay funding decisions in some jurisdictions and result in differential coverage across Canada.

In contrast, Sweden’s drug review board acts in a regulatory capacity, making final decisions about which new drugs are added to the drug benefit plan/list and pricing. In the UK, the National Institute for Health and Clinical Excellence (NICE) recommendations must be implemented by the Primary Care Trusts; that is, these Trusts are required to fund all medical technologies (including drugs) reviewed and recommended by NICE.

**Stakeholder Pulse**

When asked to identify the top three challenges with the CDR, 44% of survey respondents indicated “continued duplication of efforts” as one of them. “[Limited opportunity for patient evidence to be presented” (28%) and “How evidence is weighted in the decision-making process” (48%) were also noted.]
2. Expert Committee Representation

CDR drug recommendations are made by the CDEC, whose members are appointed by and report to CADTH’s president and CEO. Members must be qualified physicians, pharmacists, economists, or have expertise in areas such as general practice, internal medicine, hospital or community pharmacy, clinical pharmacology, pharmacoeconomics, clinical epidemiology, health services research, drug utilization expertise, methodology and/or critical appraisal, ethics or behaviour change. Despite the wide range of expertise criteria used to appoint members, it has been observed that for some reviews, clinical opinion is difficult to garner. In contrast, in the UK, epidemiologists, biostatisticians and industry representatives are formally involved in NICE. Its review bodies have established subcommittees with expertise in particular clinical areas and are permitted to consult with outside experts. Similar structures are in place in New Zealand and Australia.

Two CDEC members are public members intended to bring a lay perspective to the CDR process. The CDEC terms of reference indicate that these representatives must be members of the general public with a knowledge of or interest in healthcare and medicines and not representatives of specific interests, groups or organizations. While these terms of reference are publicly available, some groups have stated that the process for selecting public members is not clear, and there should be the opportunity for patient organizations and the public to put forward nominations to the CDEC.

Members of the general public or patient groups sit on review bodies in the UK, Australia and Sweden. In the UK, the NICE Citizens Council is an advisory (non-binding) body established in 2002 composed entirely of members of the public. An independent review of the council released in 2005 noted that while there were challenges in establishing its structure and role, “Given an appropriately concrete question, facilitation which balances the requirements of inclusivity and deliberation, and a properly supported expertise space, ordinary members of the public can contribute to a national level debate.”

3. Differences in Drug Coverage

Variation in coverage across participating drug plans continues to exist, even though respective coverage decisions are based on information obtained from the same centralized CDR review process. A 2011 Canadian Medical Association Journal (CMAJ) study noted that of 53 recommendations reviewed between 2004 and 2009, the level of overall agreement across participating drug plans with CDR recommendations was 45.2%—far below CADTH’s claim of approximately 90% of provincial/territorial agreement. British Columbia, Manitoba, Ontario and Prince Edward Island had the lowest level of agreement with CDR recommendations in their respective formulary decisions, while Alberta, Saskatchewan, New Brunswick and Nova Scotia had the highest. This is of interest given CADTH’s governance structure: it is owned by the Conference of F/P/T Deputy Ministers of Health and has F/P/T representation on its board.

According to a study by the University of Ottawa, “disagreement between CDR and provincial decisions is not random, but negatively biased away from insuring medicines that CDR recommends as cost-effective.” The authors note that this bias can be viewed in one of two ways: “furthering the public interest to save money within
a struggle of cost containment, or as injuring the public interest by denying patients treatments which are cost-effective and clinically beneficial. Other authors note potential factors beyond the CDR’s control that may impact the variance between CDR recommendations and time-to-listing decisions, such as “interjurisdictional variation in the rigour and procedures of the review process, institutional adjustments or changes at the onset of the CDR, recommendations of the Atlantic Common Drug Review, and the local values, resources and priorities of each jurisdiction.”

Internationally, review bodies use different strategies to enhance the adoption of drug coverage decisions or recommendations. In the UK and Sweden, experts and formal field-based teams are used to promote implementation at the local level. Strategies to support effective and timely implementation include additional funding and training in financial planning for local authorities and mandates for compliance.

### 4. Appeals Process

Currently, only manufacturers with drugs under CDR review can request reconsideration of a CDR recommendation. Industry has noted concerns over the appeals process—in particular, that an appeal is made to the same CDEC members who made the initial formulary recommendation. This calls into question the objectivity of the review process and the possibility of an alternative outcome. The HESA review recommended that a renewed appeals process be established to include a separate group of experts to address issues of objectivity.

In addition, there is no formal process for members of the public to raise concerns, ask questions or appeal a CDR recommendation. Patient advocacy groups have noted that appeal of a recommendation is limited to the industry manufacturer who submitted the initial application.

In contrast, Australia has an independent review mechanism for appeals. In the UK, NICE decisions may be appealed by a range of stakeholders, including manufacturers and patient or professional organizations. Appeals can be made to NICE’s Appeal Panel within 15 working days of the date of issue. Appointed by NICE’s Board, the Appeal Panel comprises five members, none of whom have had any prior involvement in the appraisal. When the date for an appeal hearing has been set, the appellant is notified. All appeals are considered in private, and only findings are made public. When appeals are upheld, often only small changes to the wording are required.

The HESA recommended that public appeals of a CDR decision be permitted; however, thus far, this recommendation has not been implemented.

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**Stakeholder Pulse**

“There is no mechanism for appeal other than the manufacturers. Patients and patient advocacy groups have at least as much interest in the outcome as manufacturers, but the design of the review makes it extremely difficult for them to have an impact on the decision.”

— Member of Project Advisory Committee

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**Given the above evidence:**

- How can the Canadian drug approval process be standardized across jurisdictions and participating drug plans to:
  - minimize duplication of efforts and differences in coverage decisions; and
  - harmonize decision-making processes and criteria?
- How can the appeal process be enhanced to better meet the needs of patients?
Review of Timelines and Access

The aim of the CDR is to provide more timely and improved access to newer and more efficient drugs, as clinically appropriate.

Key Questions

- Has the CDR led to more timely and improved access to newer, more efficient drugs, as clinically appropriate?
- Has the number of drugs covered by public drug plans increased or decreased since the CDR was introduced?

Assessment of Current System

The CDR is a distinct process in the drug access continuum, with defined deliverables and timelines. Approximately 35 submissions and resubmissions are filed with CADTH each year. These are generally new drugs, new combination products, drugs with new indications that have received a Notice of Compliance (NOC) or a Notice of Compliance with Conditions (NOC/c) from Health Canada and new drugs with a pending NOC or NOC/c (Pre-NOC Priority Review Submissions).

On average in Canada, the review process from submission to final recommendation is 4 to 6 months. The key steps and timing of the CDR process are as follows:

- Clinical and pharmacoeconomic reviews are prepared within 9 weeks.
- Reviews are provided to the manufacturer for written comments within 2 weeks.
- CDR reports are finalized, based on these comments, within 2 weeks.
- The initial Canadian Expert Drug Advisory Committee (CEDAC) recommendation and reasons for the recommendation are sent to the manufacturer and the drug plans and held in confidence for 2 weeks.
- During the 2 week period, drug plans may request clarification of the recommendation, and the manufacturer may request that CEDAC reconsider the recommendation. In such cases, CEDAC reviews the recommendation at a subsequent meeting.
- The final recommendation and reasons for the recommendation are released publicly.

A 2008 CMAJ study found that the time from Health Canada approval of a new drug to its listing on drug plan formularies has remained basically unchanged since implementation of the CDR (471 vs. 479 days), indicating that it has not delayed the coverage of new drugs. A more recent CMAJ study (2011) noted that the median time-to-listing for all drugs has decreased with the introduction of the CDR from 486 days (before) to 436 days (after). Its authors concluded that the CDR “may have contributed to a streamlining of the process for reviewing drugs for certain jurisdictions.”
Continuing Challenges

1. Differences in Length of Time for Review

While the CDR appears to have streamlined the drug review process for some jurisdictions, significant variations in the length of time exist for drug funding decisions across participating drug plans. For provinces west of Quebec, the median average review time has increased, while for those east of Quebec it has decreased. Analysis of changes across participating drug plans reveals some interesting developments:

- While Manitoba’s median time-to-listing for all drugs has increased by 24 days, it remains among the drug plans with the lowest median times.
- Conversely, while Prince Edward Island’s median time-to-listing has decreased by 691 days, it still has the highest median time across participating drug plans.
- Newfoundland and Labrador has gone from having among the highest median times-to-listing to the lowest.

While Quebec does not participate in the CDR, it continues to have the lowest median time-to-listing of F/P/T drug plans across the country.

While certain jurisdictions have seen some improvements, the shortest review times in Canada are still far longer than those in peer countries. Many countries have introduced innovative approaches to improve

<table>
<thead>
<tr>
<th>Drugs listed, no. (%)</th>
<th>Median time-to-listing for all drugs (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before CDR (n = 111)</td>
<td>After CDR (n = 87)</td>
</tr>
<tr>
<td>BC 52 (46.8) 22 (25.3)</td>
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</tr>
<tr>
<td>AB 62 (55.9) 26 (29.9)</td>
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<td>SK 73 (65.8) 35 (40.2)</td>
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<tr>
<td>ON 54 (48.6) 31 (35.6)</td>
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<tr>
<td>NB 64 (57.7) 33 (37.9)</td>
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<td>NS 61 (54.9) 31 (35.6)</td>
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<tr>
<td>NL 57 (51.4) 24 (27.6)</td>
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<td>QC 80 (72.1) 52 (59.8)</td>
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<tr>
<td>Overall 90 (81.1) 62 (71.3)</td>
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</tr>
</tbody>
</table>


i. CDR recommendations are those made on or prior to May 27, 2009.
ii. Data on decisions made by drug plan formularies are based on the version of IMS Brogan’s formulary acceptance monitoring and evaluation database dated February 2010. Source: IMS Brogan, Formulary Acceptance monitoring and Evaluation Database.
iii. Quebec does not participate in the Common Drug Review.
iv. “Overall” refers to drugs that were listed on at least one of the drug plans participating in the CDR.
v. ↑ Indicates an increase in the median time-to-listing for drugs.
vi. ↓ Indicates a decrease in the median time-to-listing for drugs.
vii. Participating drug plans are colour-coded by performance:
  - Green indicates the highest percentage of drugs approved and the lowest median time-to-listing.
  - Red indicates the lowest percentage of drugs approved and the highest median time-to-listing.
  - Middle performers are shown in yellow.
viii. Note: Gamble et al did not assess participating drug plans using these indicators; this assessment has been added as part of the adaptation from the original source data.
the timeliness of assessments and accelerate the review process to facilitate patient access to important new drugs/treatments. For example, in terms of regulatory levers to reduce geographical variation in coverage, NICE recommendations in the UK must be implemented within 3 months of dissemination. (However, compliance with this mandate has been variable.\textsuperscript{57}) In Sweden, since the TLV was set up in October 2002, all decisions have been made within 180 days. The Swedish government has set a target of 120 days for decisions on pricing and reimbursement.\textsuperscript{58}

CADTH has noted that it has no control over either the Health Canada review or decisions made by participating drug plans after a CDR recommendation has been made, and that it consistently meets its own timelines for review.\textsuperscript{59} If the CDR has not lengthened the decision-making process and may in fact have reduced timelines within some jurisdictions, the question must be asked: what factors account for the variations in time for formulary decisions taken by participating drug plans after a CDR recommendation has been made?

2. Inequitable and Limited Access to Drugs

Although a primary motivation for establishing the CDR was to provide more timely and improved access to newer and more efficient drugs as clinically appropriate, location continues to influence access to prescription medicine covered under participating drug plans.\textsuperscript{60} 

- British Columbia and Prince Edward Island had among the lowest percentages of drugs approved, and this has continued to be the case since the introduction of the CDR.
- Conversely, Saskatchewan and New Brunswick had among the highest percentages of drugs approved, and this has continued to be the case since the introduction of the CDR.
- Interestingly, Non-Insured Health Benefits (NIHB) for First Nations people changed from having among the highest percentages of drugs approved to one of the lowest after the introduction of the CDR.
- Similar to median time-to-listing, while Quebec does not participate in the CDR process, it continues to have the highest proportion of drugs listed of F/P drug plans across the country.
- Since the introduction of the CDR, the number of drugs covered by public drug plans has decreased considerably: between 47% and 66% of novel medications were listed in the five years prior to the introduction of the CDR, and between 12% and 40% in the five years after.\textsuperscript{61}

Other factors in addition to the CDR may influence this trend.\textsuperscript{62} However, factors influencing decisions are not available across jurisdictions since not all provinces post the reasons for their decisions regarding formulary listings after a CDEC recommendation has been made. Some groups have called for full disclosure by all jurisdictions of the factors and rationale underlying their formulary listing decisions based on a standardized process, including what drugs are under evaluation and commitment to time-to-listing after a CDEC recommendation has been made.\textsuperscript{63}
According to one study, in 2007 Canada ranked near the bottom of Organisation for Economic Co-operation and Development (OECD) countries when it came to providing access to new drugs for its most vulnerable citizens, including seniors and low-income families. Of 36 commonly available new drugs, the CDR recommended only 61% for public drug plan reimbursement, far less than the average of the European Union (91%) or the US (88%). Provincial formulary decisions further reduced the Canadian drug listing average: of 78 recommendations issued from the inception of the CDR in 2003 to the end of 2007, the CDR gave positive recommendations only 46% of the time.64

In 2010 it was found that for addiction treatments, women’s health, neurology, diabetes, rare disorders and mental health, “Canada’s public drug plan reimbursement is far behind that of other countries.”65 Public reimbursement for diabetes treatments is particularly low: between 2004 and July 2010, of the eight CEDAC diabetes-related indications, only 25% received positive rankings by CEDAC, compared to a Canadian average of 42% and an international average of 88%.66 No participating drug plan in Canada offers access either by full listing or restricted listing to all 24 Health Canada–approved medications. And some diabetes medications, such as certain incretin agents (which help maintain a healthy weight for people with diabetes), are not listed (either fully or with restrictions) on F/P/T drug plans.66

In contrast, another study has determined that the CDR’s record in terms of the proportion of drugs recommended for full or restricted listing or against listing a drug is similar to that of review agencies in

<table>
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<tr>
<th>Positive Reimbursement of Drugs by Disease Category</th>
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<td><strong>Therapeutic area</strong></td>
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<td>Addiction</td>
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<td>Arthritis</td>
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<td>Urology</td>
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<td>Rare disorders</td>
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<td>Mental health</td>
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Adapted from Rx&D, The Rx&D Report on Access to Medicines, 2009–2010
Positive reimbursement percentage is based on all available drugs and indications (181) available in Canada (2010).
Australia and Scotland. However, in terms of recommendations concerning individual drugs, it determined that there was poor to moderate agreement between CDR and the two other agencies, which seemed to be due to analyses of pharmoeconomic data. 68

Spending on drugs grew by 4% to $32 billion between 2010 and 2011, or 16.2% of total healthcare spending. Of this total, 61% is private spending and 39% is public spending. While drugs make up the second-largest proportion of total healthcare spending, when public funds are considered alone, drugs are the fifth largest category of spending. 69 The private sector accounted for almost 80% of expenditure for prescribed drugs in 1975; 70 this decreased to about 52% by 1992 and has remained stable since then. 71 While Canada ranks slightly above the average on the total proportion of GDP spent on pharmaceuticals, it is below the average on public spending alone. 72 This raises questions about the underlying differences in the drug review evidence and decision-making approaches used among peer OECD countries that lead other countries to more positive reimbursement recommendations compared to Canada.

Enhanced public drug coverage is important to Canadians: 93% want a renewed F/P/T accord to ensure that no one faces significant financial hardship to access drugs. 73 While efforts to establish a pan-Canadian pharmacare program have failed thus far, due partially to fears of escalating costs on the part of government, a recent study has estimated that implementation of universal pharmacare would not only make access to medicines more equitable in Canada and improve health outcomes, but also generate savings for all Canadians on prescription drugs of up to $10.7 billion. 74 Implementation of enhanced pharmacare across Canada will require strong collaboration by F/P/T governments and federal leadership.

Given the above evidence:

- How can the drug approval process be standardized across jurisdictions and participating drug plans to:
  - reduce and harmonize the length of time for making decisions across jurisdictions; and
  - reduce disparities in access?
Balance of Evidence

The CDR was established to support more evidence-based decisions via an objective and rigorous review of clinical efficacy (patient health outcomes) and cost-effectiveness (value for money), as well as patient experience for drugs in comparison with other available therapies.

Key Questions

- Has the CDR contributed to more transparent and evidence-based decision making?
- Is there an appropriate balance of information used in the CDR?
- Are mechanisms sufficient to enable patients and other stakeholders to provide evidence?

Assessment of Current System

Decision-Making Criteria

As part of the CDR process, CDEC’s approach is based on a number of key lines of evidence, including the following:

- the drug’s safety, efficacy and effectiveness compared to currently accepted therapy
- the drug’s therapeutic advantages and disadvantages relative to currently accepted therapy
- the drug’s cost-effectiveness relative to current accepted therapy
- public and patient perspectives on the impact of the drug.

Transparency

Prior to the implementation of the CDR, the detailed reasons behind drug plan decisions for formulary listings were not available publicly. Prompted by requests from drug plans, manufacturers and other key stakeholders for access to more information, the public can now monitor the status of drug submissions and review the rationale behind CDEC recommendations on the CADTH website. Key information and documents are posted to further enhance transparency and better communicate decisions and recommendations, and include the following:

- a searchable list of drugs reviewed by the CDR
- the CDEC terms of reference and meeting schedule
- the CDR Submission Guidelines for Manufacturers (developed in consultation with participating drug plans, industry and the public)
a guide for patient group input to the CDR, including details on the type of patient input CADTH is requesting, how it will be incorporated into the CDR process, and the process for submitting patient group input

• reports on the status of drug reviews as they move through the CDR process (including the targeted time frames for the review and the status of the review)

• a summary of CDEC discussions on drugs under review (i.e. key considerations, clinical trials, outcomes, results [efficacy or effectiveness], safety and tolerability, cost and cost-effectiveness, patient input information and other key points)

• an overview of the clinical and pharmacoeconomic reviews/reports

• final CDEC recommendations and the reasoning behind each (including a plain-language version)

• the names and conflict-of-interest disclosures of CDEC members participating in each review

• CDR Update news bulletins, which provide detailed information on initiatives and activities relating to the CDR process.

It has been observed that transparency of information and decision-making rationales are believed to be crucial in supporting centralized drug review; accountability and political defensibility of coverage decisions is increased when stakeholders understand the reasons for decisions.77 Equally, the goal of transparency should not merely be public access to rationales and decisions, but public understanding of rationales and decisions. If stakeholders can agree on a fair process to reach decisions, it is more likely that even if some stakeholders don’t agree with the final outcome, they will understand how the decision was reached and will be more able to accept it as legitimate and fair under the circumstances.78

Patient Input

Stakeholder involvement can also enhance the relevance of and trust in the review process.79 Increased engagement may facilitate better overall assessments, reduce the number of appeals and improve the implementation of recommendations and guidance.80 Accordingly, measures to enhance patient input into the CDR by appointing two public members to the CDEC (2006) and adding the patient group input initiative (2010) have been welcomed by key stakeholder groups.

Stakeholder Pulse

When asked to identify the top three challenges with the CDR, 48% of survey respondents noted that the top challenge was “how evidence is weighted in the decision-making process.”

“No one really knows what evidence is considered or how the evidence is weighed; the discussion of the various aspects are not made public; a deliberative process for discussion does not take place.”

Not-for-profit/community-based organization
Continuing Challenges

1. Full Disclosure of Evidence

While transparency in the drug review process has increased since the introduction of the CDR, gaps continue to exist with respect to the full disclosure of all information needed for Canadians to assess the completeness or reliability of the data on which final formulary listing decisions are based. This includes published articles used, experts consulted and clinical trial and price data.

At the request of industry, many of the technical details of the CDR review are still bound by confidentiality agreements, thereby restricting the ability of the CDR to report on the price or clinical evidence used for the CDEC recommendations. This restriction has been defined as “one of the major obstacles to transparency.”

Unfortunately, some drugs deemed safe and effective by Health Canada have later been found to have serious, even deadly side effects. This speaks to the need for the entire drug review process to consider ultimate clinical outcomes as an essential metric, such as reduction in the number of heart attacks, in addition to intermediate endpoints, such as lowering blood glucose.

2. Balancing Evidence

According to the CDEC terms of reference, the committee is to consider “therapeutic advantages and disadvantages, cost-effectiveness, and public and patient perspective on impact of the drug under review, compared to accepted therapy.” However, CADTH acknowledges that cost-effectiveness continues to be its primary consideration in determining its recommendations.

The cost of drugs is an important consideration in the drug approval process, given the need to manage limited public money available for healthcare, and competing interests and demands from both within the pharmacare and larger healthcare funding envelopes. Canada has some of the highest prices for prescription drugs among OECD countries, and total drug costs are approximately 30% more in Canada than in peer countries. Prices for generic drugs are among the highest in the world, while prices for brand name drugs are roughly within the range of prices of peer countries. Certain jurisdictions, such as British Columbia, have implemented measures such as reference-based pricing (for each therapeutic class, drug plans reimburse the cost of the reference drug, which is

Stakeholder Pulse

When asked to identify "to the best of their knowledge" what weighting the CDR currently gives to criteria as part of their review process, survey respondents noted clinical effectiveness, cost-effectiveness and therapeutic benefit as the most important.

When asked what weighting should the CDR give to criteria as part of their review process, survey respondents noted the following as the top three: therapeutic benefit, clinical effectiveness and public health impact.

Other criteria of importance included:

- equity
- societal impact
- healthcare professional perspective
- budgetary impact
- comparison with currently accepted standards of care in Canada
- input from practicing clinicians in communities across Canada regarding the gap in care for certain patients and subgroups of patients
normally the most inexpensive) to contain costs.\textsuperscript{87} Cost is consequently an inescapable factor in the decision-making process when considering the potential benefits of newer drugs compared to older ones.

However, experts consulted as part of the HESA Review highlighted the central concept that cost-effectiveness is value for money and not simply price or budgetary cost. Accordingly, the internationally accepted standard for expressing the cost-effectiveness of a new drug is the incremental cost per quality-adjusted life-year (QALY) gained, compared to other drug therapies. QALYs are a composite measure that combines quantity with quality of life. The incremental cost per QALY gained estimates the incremental cost of a new drug relative to the incremental improvements in survival and quality of life. As such, an expensive drug can still be cost-effective if it demonstrates an improved health outcome over its comparator. In contrast, a relatively inexpensive drug may not be cost-effective if it offers little or no improvement in health outcomes compared to a more costly treatment.\textsuperscript{88}

Healthcare professionals and patient advocacy groups told the HESA that the clinical and pharmacoeconomic assessment should compare not only a drug's performance to other drugs in the same class, but also to other available non-drug therapies. They suggested that the review consider a drug's impact on overall healthcare utilization. For example, if a drug reduces a patient's hospital stay, helps an otherwise disabled patient to return to work or replaces costlier or invasive procedures, this should be considered in evaluating its overall cost-effectiveness. CADTH officials clarified, however, that their assessment of cost-effectiveness does look at other costs to the healthcare system, such as doctors' visits and hospitalization. They also pointed out that the CDR has recommended some expensive drugs that demonstrate improved health outcomes.

In the Swedish reimbursement system (TLV), cost-effectiveness is analyzed from a societal perspective. This means that all relevant costs and revenues for treatment and ill health should be considered, regardless of who pays or benefits, be it the state, the county council, the municipality or the patient. When the cost-effectiveness of a drug is evaluated, all associated costs are pooled (e.g. drug costs, healthcare visit costs, costs of possible further healthcare measures, and costs due to side effects). The TLV then balances total costs against the benefits from using the drug. These benefits come in two forms: effects on health (either as a longer life expectancy or a higher health-related quality of life) and cost savings. The crucial aspect is that the drug is cost-effective, and not just for the healthcare sector, but for society as a whole. There are three criteria which must be fulfilled for reimbursement:

\textbf{Stakeholder Pulse}

According to survey respondents, “The CDR process is not transparent as it relates to how evidence is weighted and what impact the patient voice has on the outcomes of the decision.”

\begin{itemize}
  \item Industry/Manufacturer
    \begin{quote}
    “The process is not well understood by public/patient groups; many health non-profit organizations did not understand the patient input process.”
    \end{quote}
  \item Not-for-profit community-based organization
    \begin{quote}
    “CDR does not weight evidence; rather, the safety and effectiveness of the drug under review is compared with currently accepted standard of care in the Canadian context (i.e. comparative effectiveness).”
    \end{quote}
  \item Regulator/public payer
    \begin{quote}
    “Many stakeholders argue that more consideration should be given to a broader set of factors, such as disease burden, community needs and potential public health impact. In addition to including these factors in the coverage decisions, greater transparency and explicitness is needed regarding how they factor into the decision process.”
    \end{quote}
\end{itemize}
1) Human value principle: respect for the equality of all human beings and the integrity of every individual.

2) Need and solidarity principle: those in greatest need take precedence when it comes to reimbursing pharmaceuticals.

3) Cost-effectiveness principle: the cost for using a medicine should be reasonable from a medical, humanitarian and social-economic perspective.

In New Zealand, the cost-utility (cost-effectiveness) analysis of pharmaceuticals includes consideration of the following:

- effects on quality and duration of life (e.g. ability to work/perform activities, pain, anxiety, mobility)
- short- and long-term effects
- changes to the cost of pharmaceuticals
- changes to other health sector costs (e.g. hospitalizations, doctor visits)
- risks and uncertainties of the evidence available.

Potential funding options can be compared on a more or less equal basis and ranked in order of priority.

3. Consideration of Patient Experience

The experiential knowledge of patients about what it is like to live with a particular illness or condition has an important role to play in decision making; patients are uniquely positioned to make judgments on priorities and outcomes related to their health. A recent OECD study found stakeholder acceptance to be one of the key determinants of whether health technology assessment or formulary review decisions were actually put into practice in health systems.\(^9\)

Efforts to engage and involve the public in the CDR process to date are commendable. Moving forward, CADTH has noted its intention to continually assess the CDR patient engagement processes through review and evaluation to determine its impact on reviews and recommendations. In addition, CADTH seeks to develop and use new technologies in its collection and use of patient group input and its overall engagement of patients.

While public input into the CDR process has improved, limitations nonetheless include the following:

- Input from individual patients or caregivers cannot be accepted. Instead, they are encouraged to work with a patient group that represents their condition and have that patient group include their information in its submission to CDR.
- While the CDR patient input approach through patient groups is designed to allow for patients to provide input, it is not entirely clear how this input is viewed in comparison to other forms of evidence during the review process.

In contrast, the Pan-Canadian Oncology Drug Review (pCODR), established in 2010 by provincial and territorial ministries of health to assess cancer drugs and make recommendations to guide funding decisions, contains within its Expert Review Committee Deliberative Framework “alignment with patient values” as an explicit criterion, including input from its patient advocacy group throughout the review process, from pre-submission to posting of recommendations. Clinical efficacy, cost-effectiveness and the ease with which the new drug can be
adopted into participating health systems are part of this framework. Stakeholders report that the pCODR has involved patients from its inception and provides an equal balance of the interests of all parties involved, including patients.

Although stakeholder involvement may increase the resources and time required to complete a review, it can also enhance the relevance of and trust in the CDR process. In addition to the pCODR, some international practices offer useful examples:

- **User councils, consumer interest groups and committees, workshops and forums:** In the UK, NICE has established a Citizens Council to gather public perspectives on key social and ethical issues, such as whether age and disease severity should be taken into account when NICE makes decisions about treatment availability and use. NICE also uses scoping workshops to define what aspects of care the guideline will cover and to whom it will apply. Registered stakeholders are invited to submit comments on the scope and may suggest clinical questions that could be answered in the guideline. Individuals and organizations not registered as stakeholders are not able to comment.

- **Individual input:** In Australia, as part of the Pharmaceutical Benefits Advisory Committee process, comments are welcomed whether an individual is a patient, carer, member of the public, a healthcare professional or a member of a consumer interest group through online comments posted (with deadlines) on the Department of Health and Ageing website. Individuals may provide comments from a personal or group perspective for consideration by the committee. This adds a different dimension to the patient input not exercised in the other jurisdictions.

- **Collaboration with user organizations:** In Sweden, there is a User Council, in which “people who use different medicines have knowledge and experience of their use and the conditions they treat that are of fundamental importance to the decision-making process. They can also provide valuable insight into how decisions will affect users. Working closely with user representatives also allows for the provision of insight into and stimulates dialogue around review procedures.” Beyond the confines of this council in Sweden, the TLV also works closely with disabled and pensioners’ organizations that represent people affected by the review of any one pharmaceutical group.

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**Given the above evidence:**

How can the CDR ensure the appropriate balance between cost-effectiveness, clinical effectiveness and patient experience/quality of life to improve access to medications deemed safe and effective by Health Canada?
Section III: Conclusion and Recommendations

The CDR plays a critical role in the drug review process in Canada and has resulted in positive developments, including enhanced transparency, reduced length of time for reviews and improved public engagement and involvement. Nonetheless, challenges remain for the CDR. While respecting provincial/territorial jurisdiction for healthcare delivery, the Canadian Diabetes Association recommends that:

1) **The CDR, in collaboration with participating drug plans, examine national and international best practices to address challenges in the drug review process to:**
   - **Eliminate duplication in the drug review process.** Work with participating drug plans to minimize duplication of effort and differences in coverage decisions by establishing:
     - set review criteria; and
     - a drug review and regulatory process that leads to conclusions respected by each participating drug plan.
   - **Introduce greater transparency in the public engagement and review process.** Implement practices to standardize and ensure quality in the review process by:
     - ensuring an appropriate proportion of subject-matter experts for each medication under review;
     - improving the appeals process by establishing:
       - a formal appeal process for patients and patient groups; and
       - an independent appeals review body.
   - **Reduce the timelines of the drug review process.** Implement mechanisms to reduce the length of time for making decisions across jurisdictions and disparities in access, including implementation time frames.
   - **Improve the balance of the criteria used to make drug funding decisions.** Ensure the appropriate balance between cost-effectiveness, clinical effectiveness and patient experience through enhanced public engagement mechanisms.

2) **Federal, provincial and territorial governments collaborate to enhance pharmacare coverage in Canada, as committed to under previous F/P/T health accords.** Improvements such as catastrophic drug coverage and a common formulary can reduce disparities and improve access across jurisdictions, and there is evidence that such measures can also ultimately contain costs. In particular, such efforts will require strong federal leadership with appropriate incentives for provinces and territories.

We recognize that there are competing interests in the drug review process and there are advantages and disadvantages to pursuing various courses of action. There is pressure for the CDR and its provincial and territorial counterparts to make drug funding decisions more quickly, but there are also consequences from moving too quickly. Greater public engagement leads to longer review times, and there are challenges in terms of how to weigh patient experience, but it can often lead to fewer appeals of recommendations. Similarly, balancing competing interests for limited resources poses challenges and sometime difficult choices in terms of adjudicating these demands. Ultimately, we must ensure that decisions are grounded in evidence and provide the appropriate balance between clinical effectiveness, cost-effectiveness and patient experience.
Disparities in access to medications across Canada, as well as a generally lower rate of public drug plan reimbursement for certain chronic conditions, including diabetes, compromises the ability of people with the disease to self-manage their condition. The lower rate of reimbursement by public drug plans raises questions about the decision-making process underlying the CDR in comparison to others in international jurisdictions. This costs all Canadians: diabetes, its complications and poor compliance to evidence-based recommended management regimens all contribute significantly to the cost of primary healthcare and add to waiting times for treatment in emergency departments and surgeries. Indeed, diabetes cost Canada $11.7 billion in 2010; of this total, 80% can be attributed to diabetes complications.

The Canadian Diabetes Association commends CADTH for the progress made to date under the CDR process. We encourage CADTH to work closely with jurisdictional authorities, patient group representatives and industry toward further improvement and continuous change to meet the needs of all Canadians and our public healthcare system through an enhanced CDR process.
References


7. Given that private sector funding comprises the larger proportion of expenditure for pharmaceuticals in Canada (see endnote 70), the drug review process also affects private insurers. However, while pharmacare has a financial impact on both the public and private sectors through employers and insurance companies, the focus of this report is on public policy to effect change; issues concerning public coverage of pharmaceuticals will be examined in depth.


13. Ibid.


18. From submission to final recommendation.


20. The time between submission to CDR, final recommendation and when the drug is listed by participating public drug plans.

21. Cost-effectiveness is part of the deliberations of several international jurisdictions, including those reviewed in detail as part of this study (Australia, New Zealand, Sweden and United Kingdom).


25. Submission Brief to House of Commons Standing Committee on Health, op. cit.
27. Gamble et al, op. cit.
30. Submission Brief to House of Commons Standing Committee on Health, op. cit.
35. Canadian Agency for Drugs and Technologies in Health, Canadian Drug Expert Committee Terms of Reference (Ottawa: CADTH, 2011) Available at: http://www.cadth.ca/media/corporate/corp_committees/CDEC_TOR_e.pdf.
37. It should be noted that in these countries, funding decisions for drugs are made nationally. In Canada, the final decision is made at the participating drug plan level.
39. Ibid.
40. Morgan et al, op. cit.
41. Gamble et al, op. cit.
42. Prescription Drugs Part 1, op. cit.
43. Attaran et al, op. cit.
44. Ibid.
45. Gamble et al, op. cit.
46. Prescription Drugs Part 1, op. cit.
47. This is a component of the Australia–United States Free Trade Agreement (AUSFTA), a preferential trade agreement between the two countries. Key informant interview, March 2012.
49. Ibid. CDR does not accept submissions for oncology drugs. Submissions for drugs used for the active treatment of cancer are filed with the pan-Canadian Oncology Drug Review.
51. Submission Brief to House of Commons Standing Committee on Health, op. cit.
52. Tierney et al, op. cit.
53. The time between submission to CDR, final recommendation and listing by public drug plans.
54. Gamble et al, op. cit.
55. Ibid.
56. While Quebec does not participate in the Common Drug Review, median time-to-listing for this province is noted as 292 days. Ibid.
58. The TLV’s Pharmaceutical Benefits Board makes reimbursement decisions regarding parallel-imported medicinal products; new dosage strengths and packaging for medicines already granted reimbursement status; and price increases and reductions.
59. Prescription Drugs Part 1, op. cit.
62. These factors may include the therapeutic value of drugs after the introduction of the CDR. Key informant interview, March 2012.
63. Key informant interviews, March 2012.
64. Wyatt Health Management, 2007 Wyatt Health International Comparison Study (Oakville, ON: WHM, 2008) Available at: http://www.wyatthealth.com/
66. Ibid: Note: this indicator is deemed to be understated
68. “These differences may reflect both the quality of the pharmacoeconomic studies submitted to the agencies and different factors that go into these studies, including differences in the proposed price of the product, the price and effectiveness of competing products in the national markets, and the cost of hospitalization and physician visits. In addition, other considerations that may have accounted for differences in recommendations are the prevalence of the disease that the drug is designed to treat, the seriousness of the medical condition, the perceived need for the treatment, the composition of the panel making the recommendation, and the scientific rigor and relevance of evidence for comparative safety and effectiveness.” Lexchin, J., Mintzes, B. “Medicine Reimbursements in Canada, Australia, and Scotland,” The American Journal of Managed Care, 14(2008): 581–588.
69. Canadian Institute for Health Information, National Health Expenditure Trends, 1975 to 2011, op. cit.
70. Expenditures on drugs include both prescribed drugs and over-the-counter drugs for which no prescription is required. Ibid.
74. The Economic Case for Universal Pharmacare, op. cit.
78. Mitton et al, op. cit.
81. Morgan et al, op. cit.
82. Key informant interviews, March 2012.
83. Canadian Drug Expert Committee Terms of Reference, op. cit. The CDEC is the successor committee to the CEDAC within the CDR process.
84. The Economic Case for Universal Pharmacare, op. cit.
87. The Economic Case for Universal Pharmacare, op. cit.
91. The pCODR succeeded the interim Joint Oncology Drug Review (iJODR), which had provided evidence-based recommendations for cancer treatments since 2007. All jurisdictions except Quebec are members. For more about the pan-Canadian Oncology Drug Review (pCODR), see http://www.pcodr.ca/portal/server.pt/community/about_pcodr/546/review_committee/5942.
92. Key informant interview, March 2012.
93. Sorensen, op. cit.
95. This cooperative effort takes place with organizations to which the National Board of Health and Welfare has granted state contributions, in accordance with an order on state contributions to handicap organizations (2000:7) and the two largest pension organizations, the Pensioners’ National Organization (PRO) and the Swedish Association for Senior Citizens.
97. *Diabetes: Canada the Tipping Point – Charting a New Path*, op. cit.
The Canadian Diabetes Association acknowledges the generosity of the following companies for their financial support provided for the development of this Report.