



Canadian Agency for Drugs and Technologies in Health

Submission Brief to
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The Need for Drug Assessment

Drug therapy can significantly improve health outcomes for Canadians. Pharmaceuticals are also the fastest growing component of Canadian health care expenditures, increasing at approximately 10 per cent, per year.¹ The primary factors influencing drug expenditures are the increased utilization of drugs and the introduction of new, often high-priced drugs.

Assessing whether new drugs bring improved health outcomes and provide good value to Canadians is essential; that process is the Common Drug Review (CDR).

The Canadian Agency for Drugs and Technologies in Health and the Common Drug Review

Established in 1989 as the Canadian Coordinating Office for Health Technology Assessment, the Canadian Agency for Drugs and Technologies in Health (CADTH) is a national body that provides Canada's federal, provincial and territorial health care decision makers with credible, impartial advice and evidence-based information about the effectiveness and efficiency of drugs and other health technologies. CADTH has a total annual operating budget of \$24.2 million.

The Common Drug Review (CDR) is one of CADTH's three core programs. The CDR was established in 2003 by federal, provincial and territorial Health Ministers to:

- avoid duplication of drug reviews by public drug plans
- improve the quality and consistency of the review processes
- address the differences in drug coverage among the publicly funded drug plans.

The CDR funding formula is 30 per cent federal, and 70 per cent provincial/territorial jurisdiction (with the exception of Quebec). From the time the CDR was established in 2003 to present-day, the CDR budget has been \$2 million per year. As of April 1, 2007, with the expansion of the CDR to cover new indications for old drugs and increased transparency initiatives, the total budget increased to \$5.1 million.

A Unique Role on the Drug Access Continuum

Access to new drugs first requires regulatory approval by Health Canada and then is determined by patient preferences and response to therapy, physician prescribing, and formulary listing decisions made by public and private drug plans.

The CDR has a unique role on this continuum. Once Health Canada approves a drug for sale in Canada based on efficacy, safety and quality (cost is not a consideration), the drug must be submitted to the CDR if the manufacturer wishes to obtain coverage under any of Canada's public drug plans (with the exception of Quebec).

The CDR conducts 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. By providing an assessment of whether a new drug represents "value for money" from a societal point of view, the CDR helps drug plans balance access to effective treatment with fairness and affordability across the health system.

The drug plans use the CDR recommendations to make formulary listing decisions, also considering the mandate, jurisdictional priorities and resources of each of their respective drug plans. These decisions are entirely within the authority of the jurisdictions, and the CDR has no role in, or influence on, the nature or timing of decisions by drug plans.

A Rigorous Process

The CDR process begins with a drug submission from a manufacturer or drug plan. The CDR then forms a review team with the capability of evaluating the clinical and cost-effectiveness of the drug in question. The review team consists of internal and externally contracted epidemiologists, pharmacists, physicians, health economists, and information specialists. At least one physician with expertise in the relevant clinical area is included in all reviews.

In addition to the information submitted by the manufacturer, the CDR performs an independent, extensive search of the literature for its review. A systematic review of both published and unpublished clinical trials is conducted, and an economic evaluation developed by the manufacturer is assessed and critiqued. All available evidence is considered, and guidelines and templates are used to ensure a consistent, rigorous and objective approach to each review.

As part of the CDR process, manufacturers can request a priority review on the basis that the submitted drug is “effective for the treatment of an immediately life-threatening disease or another serious disease for which no comparable drug is marketed in Canada”.²

Attachment 1 provides a quick reference summary of the CDR process.

The clinical and economic reviews are considered by the Canadian Expert Drug Advisory Committee (CEDAC). CEDAC consists of 13 members from across Canada with expertise in drug therapy and evaluation. CEDAC’s approach is evidence-based, and reflects medical and scientific knowledge and current clinical practice. To ensure the general interests and views of all Canadians are represented in its work, two public representatives were appointed to CEDAC in the fall of 2006. While CEDAC is an independent committee in its thinking and perspective, it is appointed by, and accountable to, the CADTH Board of Directors.

CADTH’s jurisdictional committee pertaining to the CDR is the Advisory Committee on Pharmaceuticals (ACP). The ACP consists of members of the publicly funded drug plans and observers from health-related organizations. It provides advice to the common Drug Review on the CDR process(es). Committee members also facilitate effective jurisdictional sharing of pharmaceutical information. The ACP observers include Health Canada, the Patented Medicine Prices Review Board (PMPRB), the Canadian Institute for Health Information, and a hospital pharmacy representative.

The CDR Meets Its Timelines

Although the CDR process is highly detailed and involves many different stakeholders, the time from review initiation to recommendation is only 19 to 25 weeks. The CDR has consistently met these aggressive review timelines.

The key steps and timing of the CDR review process are summarized, as follows:

- Clinical and pharmacoeconomic reviews are prepared within nine weeks.
- Reviews are provided to the manufacturer for written comments within two weeks.
- The CDR reports are finalized, based on these comments, within two weeks.
- The initial CEDAC recommendation and the reasons for the recommendation are sent to the manufacturer and the drug plans, and held in confidence for two weeks.
- During the two-week period, drug plans may request clarification of the recommendation and the manufacturer may request that CEDAC reconsider the recommendation on the drug. In this case, CEDAC reviews its recommendation at a subsequent meeting.

- The final recommendation and reasons for the recommendation are released publicly.

Prior to the CDR, the reviews often took longer, and the level of rigour varied considerably across the jurisdictions. Evidence shows that the total time to formulary listing has not increased since before the inception of the CDR.³ This is despite establishing a standardized process that has both increased the level of rigour of the reviews and added many transparency elements to the process.

It should be noted that the timeframe for gaining access to new drugs is often reported as the total time from submission to Health Canada, to drug plan formulary listing. As previously noted, the CDR is a distinct process within the drug access continuum, with well-defined deliverables and timelines. The CDR has no influence on the Health Canada or individual drug plan approval processes. In fact, there have been time-lags of more than two years between a Health Canada approval to license a new drug and a manufacturer submitting that drug to the CDR.

CDR Recommendations Support Decisions

The success of the CDR is evident in the fact that the drug plans' decisions have followed the CDR recommendations more than 90 per cent of the time. It is important to note that this represents the rate of acceptance for those decisions which have been "made" by the drug plans. The CDR has no influence on when the drug plans make their formulary listing decisions.

The CDR is Accountable

The CDR is accountable to the Conference of Deputy Ministers of Health through the CADTH Board of Directors, whose members are appointed by, and accountable to, the federal, provincial and territorial Deputy Ministers of Health.

After one year of operation, the CDR fulfilled a commitment for an independent evaluation. The evaluation provided valuable insight into perceptions of the CDR from drug plans, health care professionals, patient groups and the pharmaceutical industry. Key recommendations were made and are being acted upon:

- To increase public involvement in the process, two public members have been added to CEDAC, and lay versions of recommendations and their reasons will be published in the coming year.
- To increase transparency in the process, the CDR is working towards publication of the review materials considered by CEDAC.
- To increase efficiencies, the CDR is implementing different options to simplify the reviews of less complex products.

A Leader in Transparency

The CDR process, procedures and submission guidelines were developed in consultation with the drug plans, industry and the public. All CDR reviewers and CEDAC members must abide by strict conflict of interest guidelines and a code of conduct.

Information posted on the CADTH web site includes: CDR procedures and submission guidelines; a search tool for drugs reviewed by the CDR; weekly reports on the status of each drug submission; biographies and conflict of interest disclosures for each CEDAC member; and CEDAC recommendations and reasons for recommendation. The publication of CEDAC recommendations, and the ability of manufacturers to review and comment on draft reports and recommendations, have established a new standard in transparency in drug reimbursement decisions in Canada.

Objectives Met

The objectives set out by the Conference of Deputy Ministers of Health for the CDR have been achieved:

- The 18 separate drug plan processes for reviewing and making formulary listing recommendations on new drugs have been replaced by one process.
- The CDR ensures all participating drug plans have equal access to high-quality reviews and expertise from across the country.
- All participating drug plans receive full CDR reports, including the recommendations and the reasons for those recommendations.
- Timelines have been consistently met.
- The CDR underwent a full evaluation after its first year, and is responding to the recommendations in the evaluation report.

The following provides a brief summary of additional CDR achievements to date:

- 94 submissions received
- 68 final recommendations issued
- drug plan formulary listing recommended for approximately 50 per cent of drugs reviewed, including innovative pharmaceuticals and biologics for a variety of disorders such as cancer, arthritis, HIV, and other serious infections
- drug plans' decisions have followed CDR recommendations 90 per cent of the time
- stakeholder consultations conducted, including regular meetings with the pharmaceutical industry
- ongoing process improvements implemented
- collaborative relations established with Health Canada and international drug reimbursement review groups.

The evaluation of the CDR concluded that the impact of the CDR on participating drug plans has, according to drug plan representatives, been wholly positive. The drug plans' perceptions were that the process is rigorous, consistent, and has reduced duplication. Drug plan representatives felt that the process is fair and transparent, and that CEDAC recommendations are clear, relevant, evidence-based and unbiased. In addition, they indicated that the CDR has resulted in increased efficiency, improved consistency, and is cost-effective.

Opportunities Going Forward

While CDR has successfully met its initial objectives, initiatives to further strengthen the program include:

- expansion of the CDR mandate to include new indications for old drugs, drug class reviews, and to contribute to the work being undertaken towards a common national formulary
- further collaboration with Health Canada on drug reviews and their proposed Progressive Licensing Framework
- integration with a framework on Expensive Drugs for Rare Diseases being developed by the National Pharmaceuticals Strategy
- participation in the Joint Oncology Drug Review – an interim national process for the review of cancer drugs, which began on March 1, 2007, to help ensure a more timely, effective and efficient review and evaluation of cancer drugs
- collaboration with the pharmaceutical industry to facilitate the review of clinical trial and economic information used by CDR
- increased transparency in the process.

Conclusion

In only three years, the Common Drug Review has established a new standard in providing Canada's public drug plans with transparent, high-quality drug reviews and formulary listing recommendations.

The CDR is evolving to meet the needs of new technologies, to expand its expertise, and to increase its transparency. The CDR is well-positioned to continue supporting the objective of the federal, provincial and territorial governments to rigorously evaluate new technologies and provide Canadians with equitable and affordable access to safe, effective, and cost-effective drug treatment.

The Conference of Deputy Ministers has recently demonstrated its strong support for the program by approving expansion of the CDR mandate, beginning in 2007/2008.

¹ Drug Expenditure in Canada 1985 to 2005, Canadian Institute for Health Information

² Procedure for Common Drug Review, February 2007

³ Provincial Reimbursement Advisor, FAME database, November 2006

Attachment 1

COMMON DRUG REVIEW PROCESS

