

**Consensus Position Statements:
Common Drug Review (CDR) Process and Policies**

**Submitted by
Best Medicines Coalition (BMC), Canadian Treatment Action Council (CTAC), and
Consumer Advocare Network**

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INTRODUCTION

The BMC, CTAC, and Consumer Advocare Network (*See Attachment 1*), submit the following position statements, issues and recommendations regarding the CDR process. As the voice of millions of Canadians living with chronic illness or conditions, we want to ensure that patients are part of the solutions to making CDR successful, and not the problem.

POSITION STATEMENTS

The Common Drug Review (CDR) process, overseen by the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), has as its primary purpose to ensure that Canadian patients access quality treatment and care in a timely manner, and a mandate to provide recommendations regarding the inclusion of new drugs into the 19 participating federal, provincial, and territorial (F/P/T) drug plans in a timely fashion.

BMC, CTAC, and Consumer Advocare Network propose that if the CDR is to be successful in achieving its purpose and mandate, CCOHTA must address:

- (1) several key CDR process issues including timeliness of processes, transparency (openness, accessibility, and accountability), objectivity and informed decision-making, appeal opportunity, and use of best clinical and other data to support decisions; and**
- (2) inclusion of relevant stakeholders including consumers in the process, through active representation and engagement on the various committees including the Scientific Advisory Panel (SAP), Pharmaceutical Advisory Committee (PAC), Devices and Systems Advisory Committee (DSAC), Common Drug Review Committee (CDRC), Canadian Expert Drug Advisory Committee (CEDAC), and CCOHTA Board. Establishing a separate Consumer Advisory Committee is also part of this position.**

BACKGROUND

- At the annual meeting of the F/P/T Conference of Ministers of Health (September 2001), an agreement had been reached to increase the collaboration for the pharmaceutical benefits plan management. Strategies included the establishment of a single, common review process for new drugs.
- In January 2002, Premiers agreed to develop common recommendations for the approval of all new drugs to be covered under provincial and territorial drug plans by the end of August 2002. An interim common review process has been in place since March 2002.

- On September 5, 2002, F/P/T Ministers of Health announced that the CCOHTA would house a new common drug review process, to enter operation in 2003. (Quebec will not be participating in this process.)
- On March 4, 2003, CCOHTA held an information session for public stakeholders. The purpose of the session was to outline the CDR process, receive feedback on the information, and identify needs of the public and ways to promote ongoing dialogue.
- The current process for all drug reviews starting in 2003 will consist of the following three phases:
 - The Drug Submission:** All new drugs will be submitted to the CDR Directorate by drug manufacturers. This submission will be submitted to all participating F/P/T drug plans, except for Quebec. The registration of this submission could take 1 – 2 weeks.
 - The Drug Review:** The CDR Directorate as part of CCOHTA will oversee the clinical and pharmacoeconomic review of the submitted and acknowledged drug. This process could take 10 – 14 weeks.
 - CEDAC's recommendation:** CEDAC will receive the scientific, clinical and pharmacoeconomic reports and will make a decision as to whether or not the drug should be recommended to be listed on the drug plan formularies, or not listed, or listed with criteria/conditions on the drug plan formularies, or the recommendation could be deferred pending further information. This process could take 6 – 8 weeks.

The total number of weeks of the drug reviews to recommendation stage is about 17 – 24. The 19 Canadian drug plan committees will make independent decisions regarding listing of the drug and the drug benefit coverage, based on their own mandate, priorities and resources. Each drug plan must also inform the drug manufacturer of its decisions. The manufacturer makes its own decision, and if the drug is not listed initially, a resubmission is treated as a new submission and goes to the end of the queue line (timing starts over).

- The following table shows the **Average Provincial Times-to-Listing: Two-Year (1999-2000) & Five-Year Data (1995-2000)** – (PRA-IMS, February 2001)

Province	2-Year Data	5-Year Data
British Columbia	310	330
Alberta	361	358
Saskatchewan	351	406
Manitoba	340	362
Ontario	460	480
Quebec	290	351
New Brunswick	394	540
Nova Scotia	366	395
PEI	448	783
Newfoundland	444	504

ISSUES AND RECOMMENDATIONS FOR SOLUTIONS

The following issues and recommendations have been identified as part of committee meetings, discussions, stakeholder and consumer reports, and other supporting documents:

1. Timeliness of Processes:

a) **Timely access** to safe and effective medications means that the CDR process should not add review time to existing processes. With CDR as proposed, there is an additional 4 – 6 months delay.

Recommendation #1: CDR should set public performance targets that will ensure the total timeline (including the estimated time for provinces to approve CEDAC’s recommendation) does not exceed the timeliest process currently in place in any of the provinces or territories.

Recommendation #2: Actual results should be compared against targets every six months, commencing with the first six months after implementation. As part of the review, the CDR Directorate should identify, as objectively and as quickly as possible, the barriers to meeting these targets.

b) **Urgency of the need of a drug** for life-threatening illnesses and breakthrough drugs as defined or determined by scientific or subspecialty committees, are in the same queue as proposed first-come, first-served drug reviews. Resubmissions of these drugs for any reason go back to the end of the line as new submissions.

Recommendation #3: Priority reviews for drugs for life-threatening illnesses and for breakthrough drugs for chronic, debilitating illnesses should have a special policy and process.

Recommendation #4: Adequate qualified staff should be hired to expedite all drug reviews and especially priority ones, within established performance targets.

2. Duplication of Information

a) **Duplication** will occur with information gathered by the CDR process, since this information is the same safety and clinical information required by the Therapeutic Products Directorate and Biologics and Genetics Therapies Directorate, Health Canada.

Recommendation #5: CDR shall automatically and timely receive from Health Canada Directorates the necessary safety and clinical data of common interest to prevent duplication of this data gathering.

b) **Additional duplication of data collection and increased delays** will result from participating drug plans not committing to dismantling their administration and expert review committees.

Recommendation #6: CDR will obtain agreement from F/P/T drug plans that they will dismantle their review administration and expert committees as soon as CDR is operational, and in the interim be subject to the timeliest performance targets set for CDR.

3. Transparency of process to stakeholders and consumers (openness, accessibility and accountability) – In order to achieve this:

Recommendation #7: CDR should develop an electronic tracking system accessible to the public and applicant, to track the review process and the CEDAC recommendations.

Recommendation #8: For transparency of the CDR process, CCOHTA's Board and other committees (SAP, PAC, DSAC, DCRC, and CEDAC), must have relevant stakeholders and consumers represented.

Recommendation #9: CDR should establish an additional Consumer Advisory Committee reporting to CEDAC, but also advising CDR on its policies and procedures and the impacts of these on patients.

4. CDR process will not necessarily provide objective information, especially if provided by the applicant. Nor will CDR access all the information required to balance cost issues, clinical outcomes, quality of life, and best medicines for patients to access. Current cost-effectiveness models lack both the validity and sophistication to take into consideration a wide range of factors. To ensure an objective and well-informed process:

Recommendation #10: CDR should ensure that a thorough and independent analysis of pharmaco-economic information (i.e. patient health care utilization, social costs, and benefit analysis), be conducted on the data provided by the applicants.

Recommendation #11: It is important to include evidence from community-based, qualitative studies, and where appropriate, experiential evidence.

Recommendation #12: The best clinical data, based on approved criteria and targeted patient groups, and including independent data sources, clinical trial outcomes, clinical practice guidelines, specialist guidelines, international experiences with medicines under review, and post-market surveillance data, must be taken into consideration by CDR.

Recommendation #13: For its review, CEDAC must seek additional information or data including expert testimony of clinical experiences, to justify its decision regarding recommendations for drugs for open, restricted, or 'not to be' listings.

5. No process for appeal exists. An appeal process must be available to consumers and other stakeholders if concerns arise with the CDR process or drug listing restrictions.

Recommendation #14: An appeal process must exist in case of concerns or complaints. The process of appeal from stakeholders to appeal committee should be open and accessible with written documentation of submissions and considerations provided to all.

CONCLUSION

In conclusion, the CDR process must be monitored and evaluated as to its success in achieving its purpose and mandate. The issues identified and recommendations proposed have been submitted by BMC, CTAC, and Consumer Advocare Network as potential solutions to ensure the success of CDR so that patients and the Canadian public will benefit.

REFERENCES

1. Information and experiences from BMC, CTAC, and Consumer Advocare Network members.
2. Romanow Commission Report – *Building on Values: The Future of Health Care in Canada. 2002.*
3. CCOHTA – Feedback & comments from the March 4, 2003 Information Session for Public Stakeholders.
4. Public Policy Forum, *Moving from Debate to Action: Securing the Future for Canada's Health System: Outcomes Report. December 2002.*
5. PRA-IMS, February 2001

ATTACHMENT 1

INTRODUCTION OF ORGANIZATIONS/AUTHORS

The Best Medicines Coalition is an alliance of representatives of a broad base of organizations and individuals working in, or promoting, education, care, research and consumer-focused advocacy and health policy for millions of Canadians living or dealing with chronic disease or illness.

The BMC's primary focus is to press for reform of Canada's prescription drug review process to improve review times; to ensure access to prescription medications in a broad based formulary; and to advocate for the implementation of an effective surveillance system to monitor the ongoing safety of a drug once it is approved and in the market place.

Best Medicines Coalition Organization Membership:

- The Arthritis Society
- Canadian Diabetes Association
- Multiple Sclerosis Society of Canada
- Cancer Advocacy Coalition of Canada
- Arthritis Consumer Experts
- Canadian Arthritis Patient Alliance
- Canadian Breast Cancer Network
- HepCURE/ Canadian Hepatitis C Network
- Canada's Association for the Fifty-Plus (CARP)

The Canadian Treatment Action Council (CTAC) is a national, non-governmental HIV/AIDS organization. The mandate of CTAC is to work with the public and private sectors to support access to therapies and treatments for people living with HIV/AIDS, provide mentoring and skills building in these areas to people living with HIV/AIDS and to encourage and facilitate the exchange of related information to stakeholders.

Consumer Advocare Network is national coalition of healthcare consumer organizations in Canada whose mission is to ensure that healthcare is driven by the needs of the consumer. Advocare seeks to promote policy and funding decisions which support consumer priorities, and facilitate consumer participation in healthcare decision making at all levels by ensuring that consumers, consumer groups and advocates are educated about healthcare issues, that consumer groups can participate in a coordinated way on issues of concern and importance, and that stakeholders work effectively with consumers, consumer groups, and consumer advocates as equal, legitimate partners.