



Guidance for Submitting Patient Group Input to the Common Drug Review and Participating Drug Plans

Introduction and Description of the Common Drug Review

Although prescription drugs contribute to improved health outcomes for many Canadians, they are the fastest growing component of the Canadian health care budget. This increases the financial pressures on the publicly funded drug plans and necessitates that they make drug coverage decisions that maximize health to the greatest extent within their available budgets. The Common Drug Review (CDR), a directorate in the Canadian Agency for Drugs and Technologies in Health (CADTH), was established as a centralized agency to provide publicly funded federal, provincial and territorial drug plans (with the exception of Quebec) with equal access to high level evidence and expert advice to assist in their decision making.

CDR, conducts reviews of drugs and provides formulary listing recommendations to the participating drug plans. The listing recommendations are made by the Canadian Expert Drug Advisory Committee (CEDAC), a CADTH advisory body composed of individuals with expertise in drug therapy and drug evaluation and of public members. In making its recommendations, CEDAC considers the clinical effectiveness, safety and cost effectiveness (value for money) of the drugs under review, compared to other available therapies. Each of the publicly funded drug plans makes its own listing decision based on the recommendation, and the drug plan's mandate, jurisdictional priorities and financial resources.

Why are drugs reviewed by CDR and drug plans?

While Health Canada approves those drugs for sale which meet its standards of efficacy and safety (usually compared to placebo) and quality, the publicly funded drug plans make decisions about which drugs they cover. To make such decisions, drug plans require evidence-based reviews of the effectiveness and cost-effectiveness of drugs, compared with existing therapies. CDR undertakes systematic, rigorous reviews of drugs and these are used by CEDAC to make common listing recommendations that assist participating drug plans with their decision making.

Which drugs are reviewed by CDR?

CDR reviews and provides listing recommendations for drugs that have been approved by Health Canada for marketing in Canada. These are generally new drugs or drugs with new indications.

What is the CDR process?

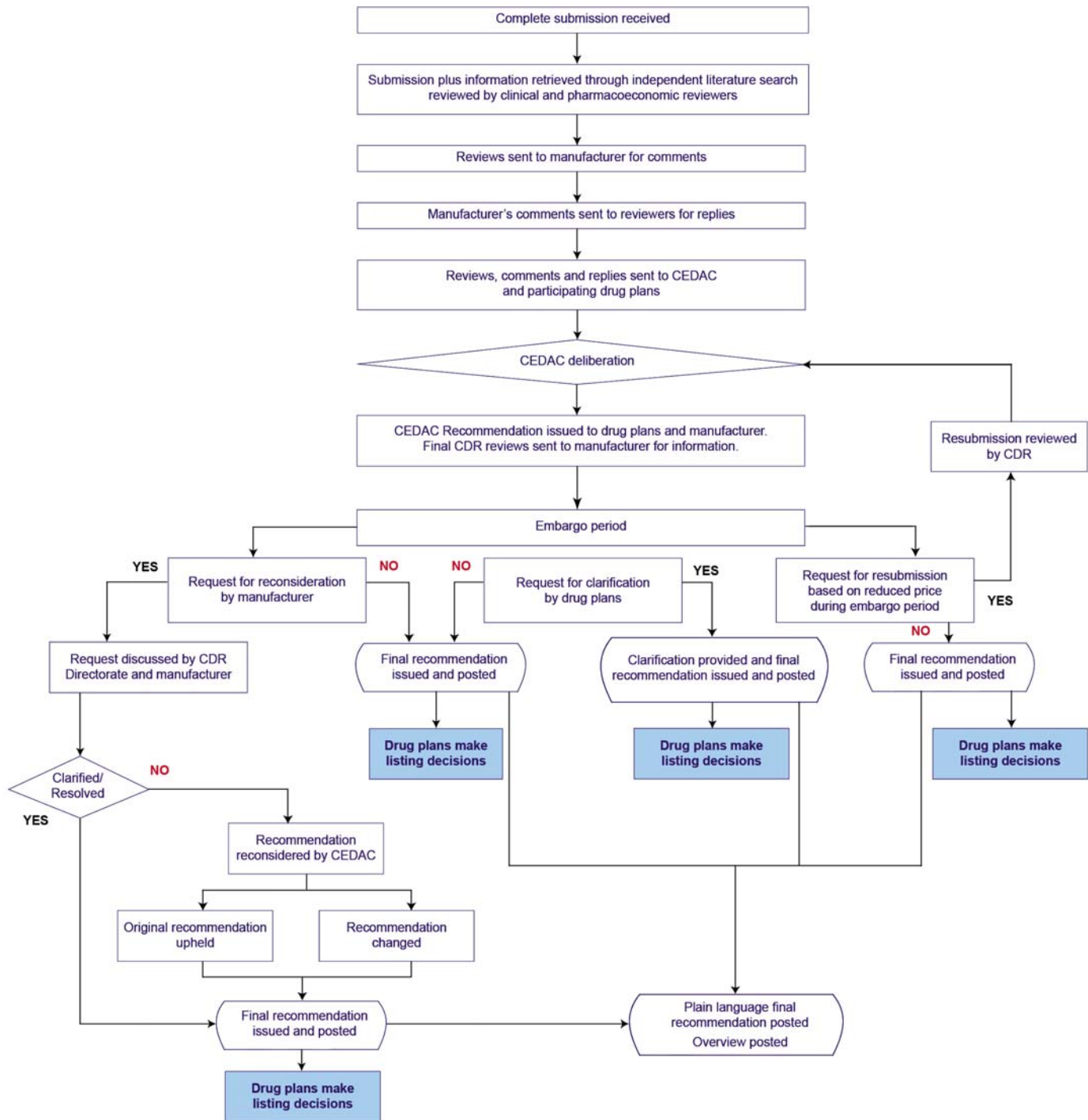
The CDR drug review process is initiated by the receipt of a drug submission from a drug manufacturer or the participating drug plans. Approximately 35 submissions and resubmissions are filed with the CDR each year. CDR reviews the available clinical, scientific and economic evidence about the drug – this includes the evidence that CDR has identified through a systematic search of the literature and also that provided by the manufacturer.

CEDAC uses the reports prepared by CDR as the basis for its recommendations. Final CEDAC recommendations are posted in the [CDR Drug Database](#) on the CADTH website.

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CDR completes the comprehensive, rigorous reviews within targeted timeframes. The total review time for a submission from the time it is received by CDR to the time CEDAC releases its recommendation is 5 to 6 months. Information about the steps in the [CDR process](#) and targeted [timeframes](#) for each drug under review can be found in the CDR section of the CADTH website, with full details contained in the [Procedure for Common Drug Review](#). See Figure 1 for a flowchart describing the CDR process.

Figure 1: CDR Review Process



CDR = Common Drug Review; CEDAC = Canadian Expert Drug Advisory Committee

General Information about Submitting Patient Group Input

The Need for Patient Input in Drug Reviews

CDR and CEDAC have access to scientific literature and research, economic analyses and specialist and expert opinions as well as public input, regarding each drug being assessed. However, currently, the patient perspective about the drug under review, or the disease for which it is prescribed, is based on the views and knowledge of the reviewers, experts and CEDAC. CADTH, the CDR-participating drug plans and CEDAC agree that the patients' perspective, or experience of living with an illness, and the impact of drug therapy on the patients' lives are important considerations for CDR reviews and the development of CEDAC recommendations.

The participating drug plans are also recognizing this need and some are incorporating patient input into their decision-making process. To this end, CDR and CEDAC have worked collaboratively with the drug plans to establish the process described in this document for systematically obtaining and using patients' inputs about the impact of the disease on their lives (for which the drug under review is indicated) and of the existing and new (if available) therapies. It is the intent that the CDR/CEDAC and drug plan processes are complementary and facilitate the collection of patient information that meets the needs of all.

Who Can Submit Patient Group Input?

Patient groups may submit written submissions to CDR about drugs that are under review, using the template for submitting patient input. Because submissions from individual patients or caregivers are not accepted, those who wish to provide input are encouraged to work with an appropriate patient group and to have that group include the information in its submission to the CDR.

How will a patient group know that a drug is under review by CDR?

1. CDR will post the names of all drugs that it receives for review on the [CADTH website](#) along with the deadline for receiving patient input. Patient groups are encouraged to check this website on a regular basis to determine if a drug that is pertinent to the group is under CDR review. (Note: Anyone wishing to follow the progress of a drug through the CDR/CEDAC process can do so by accessing the [CDR Drug Database](#).)
2. CDR will broadcast an email to subscribed patient groups, advising that a drug submission has been received. This email will include the name of the drug and some information about it such as the class of drugs to which it belongs, the indication for which it has been approved in Canada, the name of its manufacturer and the deadline date for supplying patient input. Each patient group will be responsible for determining if it wishes to provide input about the particular drug under CDR review.

Patient groups will be able to subscribe to receive notifications about new drug submissions and deadlines for patient input using the [Subscribe](#) option on the CADTH web site.

What is the timeframe for providing patient group input?

Patient input is required within 15 business days of a drug submission being received by CDR in order that the CDR reviewers can incorporate the outcomes and issues that patient groups identify as important into the review protocol. The establishment of the review protocol is a key step in the CDR review process as it clearly focuses the drug review and helps to minimize bias. Although efforts are made to incorporate patient perspective into reviews even without direct

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patient input, the real life experiences and needs of patients help to make the reviews more relevant. If the patient input is not received in time, the development of the protocol will proceed without it because the very tight timeframes for the subsequent steps of the review must be met to facilitate timely access to new drugs. (Note: subscribed patient groups will typically be advised by email on the same day as a submission is received.)

How will the patient group input be used by CDR and CEDAC?

CDR and CEDAC will use the submitted patient group input, received by the deadline date, in two main ways: it will be used by CDR to help in identifying and incorporating outcomes and issues that are important to patients in its review of the drug and it will be presented by the CEDAC public members to CEDAC for consideration in making its recommendation. Reference to the patient input may be included in the CDR reports and CEDAC recommendation; however, names of individual patients will be removed from the submitted patient input and will not appear in any CDR/CEDAC public document.

How will the patient group be informed of the CEDAC recommendation?

Patient groups will be able to follow the progress of the drug submission and see the final CEDAC recommendation via the [CDR Drug Database](#) on the CADTH web site.

How will drug plans receive and use patient input collected by CDR?

Drug plans will receive CDR-collected patient input in the following ways:

- Patient input will be reflected in the CDR review reports that are shared with all participating drug plans.
- Patient input will be reflected in the CEDAC recommendations which are used by the participating drug plans in their decision-making.
- The submitted patient input will be shared with the drug plans that request it.
- The participating publicly funded drug plans that have systems in place for using patient input may use it in their decision making.

Submitting Patient Group Input

Using the Template

A template for submitting patient group input has been developed in collaboration with CEDAC and the drug plans, and it will be posted on the CADTH website once finalized. Organized patient groups will be able to download the template, complete it and then return it by email or fax.

Email: patient.input@cadth.ca

Fax: (613) 226-5392
Attention: CDR Directorate at CADTH

Delivering the completed forms by regular mail is not recommended as the timeframe for submitting information is very short. Receipt of patient input submissions will be acknowledged.

Length of Patient Group Submission

The submission is limited to a maximum of six typed pages with a minimum 11 point font. Only the first six pages of a submission that exceeds six pages will be considered. Input should be concise and clear.

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Information Required to Complete Template

Section 1 – General Information

The following information must be provided at the beginning of the submission:

- Name of the submitting patient group and author
- Contact information (mailing address, phone number and email address) of the author / patient group
- Drug and indication(s) to which the submission pertains
- Date on which the patient input submission was prepared
- Brief description of submitting organization
- Conflict of interest declaration.

General Note: Sections 2 to 4

The information required in the following sections should be based on the real world experiences of patients living with an illness and its management and, when available, the experiences of their caregivers. **While the information should help CDR and CEDAC understand the needs and preferences of patients, individual or personal testimonials are to be avoided. Also, scientifically rigorous evidence that CDR and CEDAC can and do access from scientific literature should not be included here.**

Section 2 – Condition and Current Therapy Related Information

This section asks for comments on the nature of the condition that the drug being reviewed is for. It seeks your perspective on how the condition affects the day to day lives of patients, as well as its impact on those who give care to these patients. Further, it seeks your perspective on currently available therapy, its advantages and disadvantages, as well as whether you feel that there are sub-groups of patients who are in greater need of this medicine than the overall population of patients with this condition. Please provide us with any information you feel would be helpful for CDR and CEDAC to understand the experience patients have in living with this condition.

Section 3 – Information about Drug Being Reviewed

This section asks for your comments on the impact this drug would make if it were to be made available. It seeks your perspective on how it meets the needs and preferences of users and caregivers; its perceived advantages and disadvantages over currently available therapies and medicines; and the impact the drug may have on patients' and caregivers' lives.

Section 4 – Additional Information

This section provides the opportunity for you to submit any other information that you think would be helpful to the CDR process and CEDAC deliberations.

We are keen to learn from experience and develop as user-friendly process as possible. To this end, we would be grateful for feedback.