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1. Introduction

The Canadian Agency for Drugs and Technologies in Health (CADTH) has developed a formal approach for incorporating patients' perspectives into its Common Drug Review (CDR) process. CDR delivers formulary listing recommendations for participating publicly funded drug plans to use when making drug coverage decisions. This guide is for Canadian patient groups interested in providing input regarding drugs under the CDR review.

2. Context

The role of CADTH's Common Drug Review

CDR was established by the federal, provincial, and territorial governments to provide the publicly funded drug plans (except Quebec) with equal access to high-quality drug reviews and expert advice to support their decision-making.

CDR conducts objective, rigorous reviews of the safety and effectiveness of drugs and their cost-effectiveness (value for money) compared with other available therapies. These reviews are used by the Canadian Drug Expert Committee (CDEC) — a CADTH advisory body composed of experts in drug therapy and drug evaluation, and of public members — to make formulary listing recommendations to the drug plans.

Drugs reviewed by the Common Drug Review

CDR generally reviews new drugs or drugs with new indications.

Typically, CDR reviews drugs that have been approved by Health Canada for marketing in Canada. The document Health Canada issues when granting marketing approval for a drug is called a Notice of Compliance (NOC) or Notice of Compliance with conditions (NOC/c).

CDR will review a drug prior to Health Canada approval when it is submitted by the manufacturer for pre-NOC Priority Review and it meets the criteria for priority review. Pre-NOC priority reviews are designed to potentially accelerate access to publicly funded medications without compromising the high quality of CDR reviews.

A note about Health Canada's role

Health Canada authorizes the sale of drugs in Canada based on its review of the scientific evidence of their safety and efficacy, and a review of their quality, as defined by regulations. Health Canada does not consider the cost of drugs. If Health Canada determines that the potential benefits of a product outweigh the risks associated with it and it meets quality standards, it is approved for sale in Canada.

Public drug plans

Publicly funded drug benefit programs have been established in each of the Canadian provinces and territories, and in some federal departments. All of the publicly funded drug plans, with the exception of Quebec, participate in CDR. The plans make decisions about which drugs are covered as benefits by their programs. They use the CDR reviews and CDEC recommendations, and also consider their own drug plan mandate, jurisdictional priorities, and financial resources when making their individual listing and coverage decisions.

3. The CDR Process

Initiation: The review process starts when CADTH receives a submission from a drug manufacturer or the participating drug plans. Approximately 35 submissions and resubmissions are filed with CADTH each year.

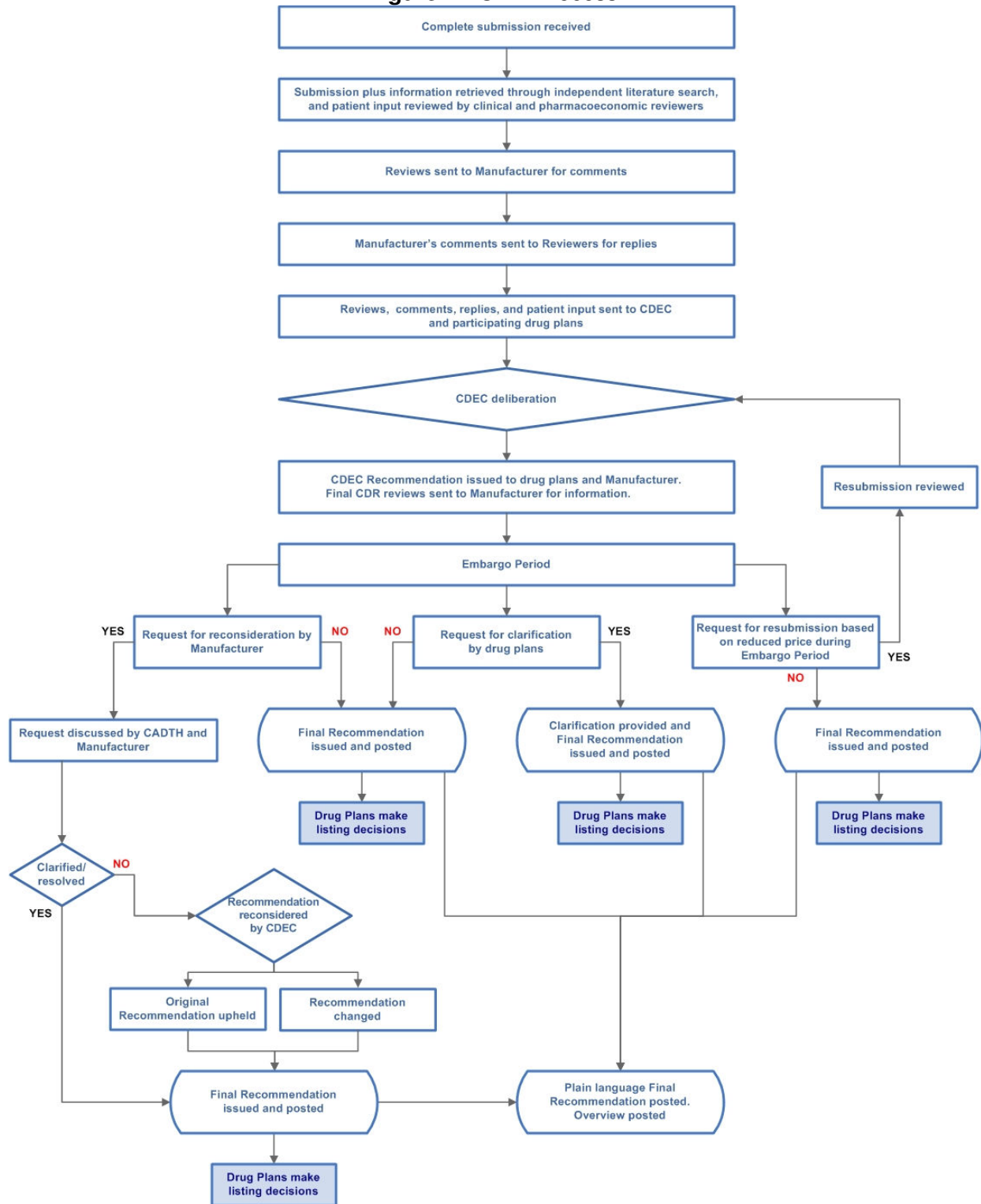
CDR review: CADTH reviews the available clinical, scientific, and economic evidence about the drug, compared with alternative therapies. This includes evidence CADTH has identified through a systematic search of the scientific literature, the information provided by the manufacturer, and input from specialists and patient groups. Based on this evidence, comprehensive, rigorous clinical and economic reports are prepared.

CDEC recommendations: CDEC uses the comprehensive reports as the basis for its recommendations. For each drug, CDEC considers the clinical effectiveness, safety, cost-effectiveness (value for money), as well as public and patient perspectives, on the drug's impact compared with other available therapies. Final CDEC recommendation documents are posted in the [CDR Drug Database](#) on the CADTH website and are accessible by the public.

Industry: Manufacturers have the opportunity to comment on the review reports and the CDEC recommendations, and to request reconsideration of recommendations.

Timelines: CADTH completes the entire CDR review process within tight targeted time frames. The total review — from the time a submission is received by CADTH to the time the CDEC recommendation is released — is five to six months. The steps in the [CDR process](#) and targeted [time frames](#) for each drug under review can be found in the CDR section of the CADTH website; full details are contained in the [Procedure for Common Drug Review](#). Figure 1 illustrates the CDR process.

Figure 1: CDR Process



CDR = Common Drug Review; CDEC = Canadian Drug Expert Committee

4. Patient Group Input

Importance of patient group input

For each drug being assessed, CADTH and CDEC have access to the pharmaceutical manufacturers' submission and other independently identified scientific literature and research, as well as specialist or expert opinions. Prior to the implementation of the patient input initiative, a formal method for incorporating patient perspectives on the drug or the relevant condition was not part of the CDR process. The patient group input initiative ensures that this important information is systematically incorporated.

How patient group input is used in the CDR process

Submitted patient group input is forwarded in its original, unedited format and also collated and forwarded as a summary:

- to the CADTH review team, so that it can incorporate health outcomes and issues identified by patients into the planning for the drug review and into the CDR clinical and economic review reports
- to CDEC, to consider along with the clinical and economic information when making the recommendation. CDEC public members review and present the patient group input to CDEC during its deliberations.

Public drug plan use of patient group input

The participating public drug plans also recognize the need for patient input and some are incorporating patient input into their decision-making process. To this end, CADTH and the expert advisory committee worked collaboratively with the drug plans to establish the process described in this document. It is the intent that the CADTH and drug plan patient input processes are complementary and facilitate the collection of patient information that meets the needs of all.

How public drug plans receive the input

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

- Patient group input is reflected in the CDR review reports, which are shared with all participating drug plans.
- All patient group submissions are shared in their entirety with the drug plans and CDEC.
- Patient group input is reflected in the CDEC recommendations, which are used by the participating drug plans in their decision-making.

5. Submitting Patient Group Input

Who can submit input?

Patient groups may provide written submissions to CADTH about drugs that are under CDR review, using the *Template for Submitting Patient Group Input to the Common Drug Review at CADTH*.

Submissions from individual patients or caregivers are not accepted. Individuals who wish to provide input are encouraged to work with a patient group to have that group include the information in its submission.

When to submit patient group input to CADTH

- **CADTH website:** CADTH posts the name of a pending or received drug submission, the name of the manufacturer, the indication for which the drug has been approved, and the deadline for supplying patient group input on the [Patient Input](#) page of the CADTH website.
- **Subscribe to e-notifications:** CADTH also emails all subscribers “Calls for Patient Input” to advise them of pending and received drug submissions to CADTH. These e-alerts are typically sent out within several hours of CADTH receiving a submission or notice of a pending submission. Patient groups and individuals are encouraged to subscribe to these notifications using the [Subscribe](#) option on the CADTH website.

Time frame for providing input

Patient groups are requested to provide input within **15 business days** (i.e., three weeks) of CADTH receiving a manufacturer or drug plan submission. If the manufacturer provides advance notice of the submission, the patient deadline is extended by the number of business days of advance notice (maximum 10 days), increasing the deadline to a maximum of 25 business days. (Note: Manufacturer notification to CADTH of pending submissions is voluntary.)

This timing ensures the input has the maximum impact on the CDR review process. The early receipt of patient group input allows the CADTH reviewers to incorporate into the review protocol outcomes and issues that are important to patients. The protocol development is a critical step, early in the review process, that provides the plan for the drug review.

Steps for submitting patient group input to CADTH

1. **Review** this guide for general information about 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.
2. **Download** the *Template for Submitting Patient Group Input to the Common Drug Review at CADTH* from the [Patient Input](#) page on the CADTH website. It includes specific examples of information that is useful to the CADTH review team and CDEC.
3. **Complete** the template in English with the suggested information (see details that follow and details in the template).
4. **Submit** the completed document on the CADTH website using the “Submit” link in the table on the [Patient Input](#) page. The brief online form will allow you to upload your completed file. Those who file a submission online receive an immediate automated email acknowledgement, which confirms the time of receipt by CADTH and the submission contents.

Alternatively, the completed template may be faxed to CADTH, Central Intake.
(Fax no.: 613-226-5392.)

Due to the tight time frames, the online submission option is strongly recommended.

If you have any questions about the patient input initiative or a patient group submission, please contact CADTH, Central Intake, by telephone at 613-226-2553 or by email at requests@cadth.ca.

Submission length and format

Patient group input should be clear and concise, and kept to a maximum of six (6) typed pages (with a minimum 11-point font). If a submission exceeds six pages, only the first six will be considered. We suggest that you delete the questions and examples under each heading for more space when completing each section of the template.

Submissions should be filed in English, with electronic submissions submitted as a Word document, to facilitate incorporation into the CDR reviewers' reports.

Tracking a CDR review and recommendation

The progress of a drug through CADTH's CDR process may be followed using the [CDR Drug Database](#) on the CADTH website, specifically the *Submission Status Reports*. Final *CDEC Recommendations* are also posted in the database. The information in the database may be sorted in a variety of ways. The sort by "Indication" (condition) may be of particular interest to patients.

6. Template Information

Information to complete the template

Section 1 — General Information

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

- Name of the drug submission to CADTH, and indication(s) of interest
- Name of patient group, primary contact, and author (if different)
- Contact information for the primary contact and the patient group (email, phone number, and mailing address)
- Brief description of the submitting organization
- Conflict of interest declaration (declarations of conflict of interest are requested for transparency and will not preclude the input from being considered). The names of all manufacturers who have provided funding should be listed, not just the manufacturer of the drug under review.

Sections 2 to 4 — General Notes

The information provided should be based on real-world experiences of patients living with a condition and its management, and, when available, the experiences of their caregivers. The information should help CADTH and CDEC understand the needs and preferences of the majority of patients. Objective, experiential information that is representative of most in the patient group is most useful.

Patient groups do not need to submit published information, as CADTH and CDEC have access to current scientific literature through the manufacturer's submission and a rigorous, independent literature search. However, relevant unpublished studies may be submitted in addition to the template.

Section 2 — Condition and Current Therapy Information

This section asks for comments on the nature of the condition that the drug being reviewed is intended to treat. It seeks perspectives 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 perspectives on currently available therapy and its advantages and disadvantages, as well as

whether there are subgroups of patients who are in greater need of this therapy than the overall population of patients with this condition. Please provide us with any information you feel would be helpful for CADTH and CDEC to understand the experience patients have in living with this condition.

Section 3 — Information about the Drug Being Reviewed

This section asks for comments on the anticipated impact this drug may have. For those who have used the drug being reviewed, this section seeks your perspective on how the drug 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 to submit any other information that would be helpful to CADTH's review process and CDEC deliberations.

7. Privacy

Patient group input will be used during CADTH's review process and by CDEC.

- It will be shared with the participating publicly funded drug plans.
- It may be used in publicly available documents.
- Personal information will not be made publicly available.

8. Feedback

CADTH is keen to learn from experience and develop the most user-friendly patient group input process. We would be grateful for feedback, which may be submitted to feedback@cadth.ca.