CONSULTATION DOCUMENT

The Canadian Agency for Drugs and Technologies in Health (CADTH) has collaborated with participating drug plans and the Canadian Drug Expert Committee (CDEC) to revise and clarify the Common Drug Review (CDR) recommendation options and to describe more fully the CDEC deliberative process. The finalized information will be incorporated into the Procedure for Common Drug Review and will guide CDEC in making listing recommendations, with the recognition that CDEC will have the flexibility to adapt these guidelines on a case-by-case basis. CADTH will implement the revised CDR recommendation options and CDEC deliberative process at the November 21, 2012 CDEC meeting, starting with new drug submissions or resubmissions. CADTH is inviting stakeholder comments and feedback on the Revised Common Drug Review Recommendation Options and Canadian Drug Expert Committee Deliberative Process.

Part I. Revised CDR Recommendation Options

The revised CDR Recommendation options are described below.

<table>
<thead>
<tr>
<th>Recommendation Options</th>
<th>Description and Considerations</th>
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<tbody>
<tr>
<td>List</td>
<td>• A drug* demonstrates clinical benefit and comparable clinical effectiveness, and acceptable cost/cost-effectiveness relative to one or more appropriate comparators.†</td>
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<tr>
<td>List with clinical criteria and/or requirements</td>
<td>Examples of scenarios that fit this listing category include:</td>
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<td>• A drug* demonstrates clinical benefit and comparable clinical effectiveness, and acceptable cost/cost-effectiveness relative to one or more appropriate comparators in a subgroup of patients within the approved indication. In such cases the subgroup is specified through “clinical criteria.”</td>
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<td>• A drug* demonstrates clinical benefit and comparable clinical effectiveness, but the cost/cost-effectiveness relative to one or more appropriate comparators is unacceptable. In such cases a “requirement” may include a reduced price.</td>
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<td>• An existing comparable drug for the approved indication† demonstrates clinical benefit and acceptable cost/cost-effectiveness relative to one or more appropriate comparators. In such cases a “requirement” may include that the drug* be listed in a similar manner to one or more appropriate comparators.</td>
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<td>Examples of clinical criteria include:</td>
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<td>• characteristics that identify a patient subgroup (e.g., comorbidity status, inadequate response, or intolerance to relevant comparator[s])</td>
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|                        | • characteristics of the care setting (e.g., prescribed by or under the care of an experienced clinical team)  
• starting and stopping rules (e.g., response to treatment). |
|                        | Examples of requirements include:  
• pricing considerations  
• reimbursement limits  
• formulary listing status of one or more appropriate comparators  
• evidence development  
• collection of utilization data. |
| Note:                 | The use of “and/or” in the “List with clinical criteria and/or requirements” allows for three subcategories of this listing category:  
• clinical criteria and requirements  
• clinical criteria only  
• requirements only. |

**Do not list at the submitted price**  
An example of a scenario that fits this listing category includes:  
• An existing comparable drug for the approved indication demonstrates comparable clinical benefit, but the cost/cost-effectiveness relative to one or more appropriate comparators is unacceptable.  

**Note:**  
The “Of Note” section in the recommendation may provide additional context around price, comparator(s), patient subgroups to whom the drug might be restricted, and other relevant considerations.  

**Do not list**  
• A drug* does not demonstrate clinical benefit or comparable clinical effectiveness. In such cases there is no reason to list, regardless of price.  

*Refers to a drug under review.  
†An appropriate comparator is commonly a drug listed by one or more CDR participating drug plans at the time of the CDEC review.  
‡An existing comparable drug is one that is approved for the same indication and typically belongs to the same therapeutic class as the reference comparator(s). Non-inferiority designs are frequently employed in clinical trials of “me too” drugs.  

### Part II. CDEC Deliberative Process

**Background:**  
CDEC is an advisory body that makes drug-related recommendations and provides drug-related advice to CADTH. Recommendations and advice from CDEC are provided to CADTH to inform key clients and a range of stakeholders.  

**CDEC Membership:**  
CDEC comprises 11 to 14 members, including the Chair. Two of the members are public members, tasked with bringing a lay perspective to the Committee and ensuring that patient concerns are accorded important consideration in CDEC discussions and deliberations.
Engagement of CDEC Members in the CDR Review Process:

CDEC members declare all conflicts of interest before deliberations on each submission in accordance with the Conflict of Interest Guidelines for CADTH Expert Committee and Panel Members. All CDEC members at a CDEC meeting (either in-person or by teleconference) must vote unless precluded by conflict of interest.

Before a CDEC Meeting:

- For each drug submission, a CDEC brief is made available to all members of the Committee two weeks before the CDEC meeting. Materials contained in a CDEC brief include, but are not limited to:
  - patient group input
  - submission history table of similar drugs reviewed by the Canadian Expert Drug Advisory Committee/CDEC
  - CDR Clinical Reviewers’ Report
  - manufacturer’s comments on clinical report and clinical reviewers’ responses
  - Pharmacoeconomic Reviewers’ Report
  - manufacturer’s comments on pharmacoeconomic report and pharmacoeconomic reviewers’ responses
  - drug plan listing status for comparators
  - additional information
    - reference material (for clinical and economic review reports)
    - manufacturer’s disclosure of ongoing trials
    - Manufacturer’s Executive Summary.
- Three CDEC members, including one public member, are assigned as “discussants” for each drug submitted to the CDR early in the review process. The discussants prepare brief written overview reports based on patient group input, clinical and economic reports, and the materials contained in the CDEC brief. No new clinical or economic information — i.e., information that was not submitted or included in the review of the submission or resubmission — is included in the overview reports.
- Discussant reports are reviewed by CADTH staff for accuracy and are subsequently provided to all CDEC members in advance of the meeting.

CDEC Meetings:

Attendees

In addition to CDEC members, the following persons may attend a CDEC meeting:

- health ministry officials, appointed by participating jurisdictions, who attend as observers, but do not participate in deliberations or voting
- experts, such as clinical specialists, methodologists, economists, who may be invited to answer questions, but do not participate in deliberations or voting
- CADTH staff and contractors employed in the review who may present information relevant to the submission and/or provide administrative and secretariat support, but do not participate in deliberations or voting.

CDEC Deliberative Process

- For each drug submission, discussants present their reports.

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1 Therapeutic Review and Optimal Use reports prepared by CADTH are included in CDEC briefing materials when relevant.
• The public member makes the first presentation, which is a summary of patient group input and includes the stated values and preferences and issues of patients and/or their caregivers related to the condition for which the drug is indicated and its treatment.

• The other two CDEC discussants present their overviews of the clinical and economic evidence.

• Following the discussant presentations all CDEC members provide input; and CDR staff, including clinical and economic reviewers, and invited experts provide input as required.

• If CDEC needs additional information or clarification, either from the reviewers or from the applicant, or from external experts, the matter will be sent back to CADTH to collect the additional information or clarification and the matter will be deferred to a subsequent CDEC meeting, pending the collection of such information. (Note: additional information does not include any new information that was not submitted or included in the review of the submission or resubmission.)

• CDEC members deliberate the patient group input, clinical and economic evidence, and formulate a recommendation and provide reasons for it.

• Based on the deliberation of the available evidence, CDEC members choose one of four recommendation options as described in Part I above: List, List with clinical criteria and/or requirements, Do not list at the submitted price, or Do not list.

• CDEC members then vote on the recommendation.

Voting

• Ballots are circulated for voting.

• Only CDEC members vote. All CDEC members must vote unless there is a declared conflict of interest that precludes a member from voting.

• The CDEC Chair votes only in the case of a split vote.

• CDEC members vote by secret ballot on the recommendation option and the reasons for the recommendation. Every CDEC recommendation is decided by a majority of votes. The Chair validates the results of voting and announces if the motion is carried.

• CDEC must make a recommendation or defer if additional information or clarification is needed.

Post-CDEC Meeting

Following the meeting, the draft recommendation document is finalized by CADTH staff with input from CDEC members. After approval by the CDEC Chair, the embargoed recommendation is distributed to the CDR participating drug plans and the drug manufacturer, and subsequent steps of the review process are followed in accordance with the current Procedure for Common Drug Review.