

## Transparency of the Drug Review Process

In recent years, the Ministry of Health and Long-Term Care has introduced a number of measures to increase the transparency of Ontario's drug submission review process and to keep stakeholders informed of the recommendations made in respect of drug submissions to the Ministry by the Committee to Evaluate Drugs [CED – formerly the Drug Quality and Therapeutics Committee (DQTC)]. The CED has always been supportive of sharing their recommendations with stakeholders. Making the CED recommendations public will provide a rational and balanced representation of the value of new drugs and improve accountability, to counter the current perceptions of secrecy in decision making.

In furtherance of this objective, the Ministry has established a website on which it will post summaries of the recommendations made by the CED to the Executive Officer of the Ontario public drug programs (the "Executive Officer").

Upon full implementation of the Ministry's transparency initiative, this will enable interested members of the public to not only monitor the status of drug submissions as they proceed through the review process but also to review the reasons underlying the listing recommendations made by the CED.

## Implementation of Increased Transparency

This transparency initiative will be implemented in phases. In the first phase, the Ministry will post summaries of the CED's recommendations, including whether the recommendation was based on clinical or cost-effectiveness considerations, for all submitted single-source products on a go-forward basis, starting with the submissions reviewed at the October 2006 CED meeting. These recommendations can be accessed at:

[http://www.health.gov.on.ca/english/providers/program/drugs/odbf\\_mn.html](http://www.health.gov.on.ca/english/providers/program/drugs/odbf_mn.html)

In the second phase, the Ministry will begin posting information regarding the status of single-source submissions as they progress through Ontario's drug review process. Subsequently, the Ministry will examine the feasibility of posting past recommendations of the DQTC. Should the Ministry decide to post past recommendations of the DQTC, it will notify manufacturers of product bulletins that it intends to post.

The posting of CED recommendations in respect of certain multiple-source and other products will be assessed on a case-by-case basis where the information may be of interest to stakeholders.

The CED recommendation summaries, which will be posted on-line ("Posted Summaries") will consist of the following:

- Recommendation "highlights" in bullet point.
- Details of the CED recommendations and supporting rationale, including information regarding the efficacy and safety of a drug product compared to currently available alternatives.
- Discussion points concerning the appropriate patient group for the drug product reviewed (and, conversely, patient groups for whom the product should not be prescribed).

- Alternative drug products that are listed on the Formulary.
- Discussion points regarding the cost-effectiveness of a drug product and/or cost comparisons to alternatives.
- Discussion points regarding clinical studies of the drug product reviewed.
- Links to the Common Drug Review/Canadian Expert Drug Advisory Committee website (where applicable), or the Cancer Care Ontario (CCO) website for oncology products reviewed under the joint CED/CCO subcommittee process.

The Posted Summaries may include the following types of information:

- Published information.
- Unpublished data/information available in poster or abstract form or obtained from a source other than the submitting manufacturer.
- Comparative analyses by the CED regarding the efficacy, safety, price, and cost effectiveness of submitted drug products versus alternatives.
- Estimated costs per quality-adjusted life year (QALYs), and qualitative comments regarding the CED interpretation of the cost-effectiveness data.

The following types of information will not be included in the Posted Summaries:

- Unpublished data/information supplied by the submitting manufacturer that is not otherwise available in the public domain and which has been explicitly designated as confidential, unpublished information by the submitting manufacturer.
- Budget impact analyses submitted by manufacturers.
- Financial details of manufacturers' listing and pricing agreements with the Ministry.

## Confidentiality

The Ministry will endeavour to continue to hold all manufacturer submissions in confidence. Only the CED recommendation and rationale will be publicly available; however, the information posted on the Ministry's website will be based on the CED review of the manufacturer's submission. As a consequence, information provided by the manufacturers in their submission may be made public. The Ministry will consult with the Privacy Commissioner regarding any limitations on current exemptions under the *Freedom of Information and Protection of Privacy Act*, given the disclosure of the CED recommendations and rationale, which considers manufacturer-submitted information. This will be followed by consultations with pharmaceutical manufacturers if changes are necessary.

The Ministry will consult with the Privacy Commissioner regarding the release of reviewer's reports to the public under the *Freedom of Information and Protection of Privacy Act*, prior to any policy decisions being made.

## Process for Posting CED Recommendations

STEP	ACTIVITY	TIMING
1	CED recommendation is made at each CED meeting.	Monthly (usually 2nd Wednesday of each month)

2	Recommendation letter is sent to the submitting manufacturer. The content of the letter is based on the CED meeting minutes.	Usually 2-3 weeks after the CED meeting.
3	The posted CED summaries will be based on the recommendation letters that are sent to submitting manufacturers. Manufacturers may provide comments on the letters to the Ministry.	After receipt of the CED recommendation letters
4	CED summaries are: <ul style="list-style-type: none"> <li>i. prepared by DPB and reviewed by the CED consultant or lead presenter;</li> <li>ii. are ratified at the next CED meeting</li> </ul>	One-month period between CED meetings.
5	Any manufacturer comments to the CED recommendation letter, including identification of errors, received prior to ratification of the minutes, are considered; at the Ministry or CED's discretion, revisions or an addendum to the posted CED summaries could be made to correct a material misrepresentation or to indicate that the manufacturer has provided additional information that will be further reviewed.	During the one month period between CED meetings.
6	CED summaries are posted on the Ministry website at any time after ratification of the CED minutes.	Approximately six weeks after CED recommendation.

The Drug System Secretariat is currently developing a Fairness Review process in respect of Formulary listing decisions made by the Executive Officer.