

Transparency of the Drug Review Process

One of the key commitments from Bill 102: *The Transparent Drug System for Patients Act, 2006* is to provide clear communications about drug funding recommendations and the rationale for decisions to patients, prescribers and manufacturers. In addition, the Ministry's expert advisory committee, the Committee to Evaluate Drugs (CED), has always been very supportive of sharing their recommendations with stakeholders. Making the CED recommendations public provides a rational and balanced representation of the value of new drugs. Improving transparency of the drug review process also improves accountability of the decision making process.

Further to the Bill 102 commitment to increased transparency, the public can now monitor the [status of drug submissions](#) and review the rationale for the [Executive Officer's decision and the CED recommendations](#).

The CED recommendations and rationale posted on the Ministry's website will outline:

- Summary "highlights" in bullet point.
- Details of the CED's recommendations/rationale, with information regarding efficacy and safety compared to currently available alternatives.
- A discussion of clinical studies.
- Alternative medications available (specifically ODB Formulary alternatives).
- A discussion of cost-effectiveness and/or cost comparisons to alternatives.
- Links to the CDR/CEDAC website or the CCO website for oncology products reviewed under the CED/CCO subcommittee process (where applicable).
- The Executive Officer's final decision and funding status.

Information which may be included:

- Comparative analyses by the CED and/or Ministry consultants regarding the efficacy, safety, price, and cost-effectiveness of submitted drug products versus alternatives.
- Published information, including data that was unpublished at the time of the manufacturer's submission but has since become published at the time of posting the CED recommendations.
- Unpublished data/information available in poster or abstract form or obtained from a source other than the manufacturer.
- Estimated costs per quality-adjusted life year (QALYs).
- Funding criteria, if applicable.

Information which will not be included:

- Unpublished data/information submitted by manufacturers in confidence that is not otherwise available in public domain.
- Budget impact analyses submitted by manufacturers.
- Details of manufacturer's agreements with the Ministry. Commercial prices will be published as appropriate.
- Common adverse events or side effects that were not discussed by the CED.
- Medical diagnosis, symptom assessment, health counselling, and medical opinions/advice for individuals.

Confidentiality

1. Manufacturer's Submissions

Under the transparency initiative, the information posted on the Ministry's website will be based on the CED's review of the manufacturer's submission. The information provided in the manufacturer's submission will continue to be held in confidence; only the CED recommendation and rationale will be publicly available.

2. Reviewer's reports

Technical portions of reviewer's reports may be released only to the submitting manufacturer upon request.

3. Freedom of Information

The Ministry will continue to 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's 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 report to the public under the *Freedom of Information and Protection of Privacy Act*, prior to any policy decisions being made.