

# THE DRUG REVIEW PROCESS IN B.C. — DETAILED

## PURPOSE

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Under the PharmaCare program, the Ministry of Health Services seeks to provide coverage for drugs that support the health and well-being of British Columbians and provide value for money.

Before a drug can be included in the PharmaCare formulary, it undergoes a thorough review to determine whether it meets these two requirements. The review process helps ensure that the PharmaCare program remains fair, effective, and continues into the future.

## DRUG REVIEW PROCESSES

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In Canada, the drug review processes take place in three stages.

### Stage 1 – Health Canada (federal government)

All drugs sold in Canada must have received a Health Canada Notice of Compliance (NOC). Before issuing an NOC, Health Canada reviews:

- the drug's safety,
- the effect of the drug when compared to taking no drug at all, and
- the quality of the manufacturing process used to make the drug.

For more information on Health Canada's drug review process, visit their website at [www.hc-sc.gc.ca/dhp-mps/prodpharma/index-eng.php](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index-eng.php).

### Stage 2 – Common Drug Review (national review)

To have their patented drugs<sup>1</sup> covered by public sector drug plans, drug sponsors must send a submission to the Common Drug Review (CDR), a process administered by Canadian Agency for Drugs and Technologies in Health (CADTH)<sup>2</sup>. Drug submissions reviewed by the CDR include new drugs introduced in Canada or new Health Canada approved uses of existing drugs.

The CDR process reviews:

- how well the drug works when compared to similar drugs that are used to treat the same condition, and
- whether the drug provides value for money.

A team of independent experts is assembled to review each drug; based on their findings, a recommendation on whether or not drug plans should cover the drug is issued.

For more information about CADTH and the CDR, visit their website at [www.cadth.ca/index.php/en/cdr](http://www.cadth.ca/index.php/en/cdr).

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<sup>1</sup> Including new drugs; new combination drugs; subsequent entry biologics (SEBs); and new uses for existing drugs.

<sup>2</sup> Except for Québec which uses a different drug review process.

## Stage 3 – Ministry of Health Services Drug Review (B.C. review)

The Ministry conducts its own review before making its coverage decision. This review builds on the work done by Health Canada and the CDR process. The Ministry does not duplicate the work of the CDR.

For more information on patented drug submission requirements, visit the PharmaCare website at [www.health.gov.bc.ca/pharmacare/formulary/drugsub.html](http://www.health.gov.bc.ca/pharmacare/formulary/drugsub.html).

### ***Improvements to the B.C. Review process***

In February, 2010, the Ministry of Health Services enhanced and improved the drug review process by:

- making the process more transparent and accessible, keeping stakeholders more informed
- gathering more information from health professionals
- speeding up the review times (*see below for details*)
- expanding the advisory Council, the Drug Benefit Council, to include three members from the public (*see below for details*).
- establishing new process components to review drugs (*see Drug Review Resource Committee and Drug Review Resource Teams activities below*)
- updating the drug submission requirements, including simplifying requirements for less complex submissions
- adding new opportunities for drug submission sponsor engagement

Enhancements are ongoing. Further details will be provided as more improvements are made.

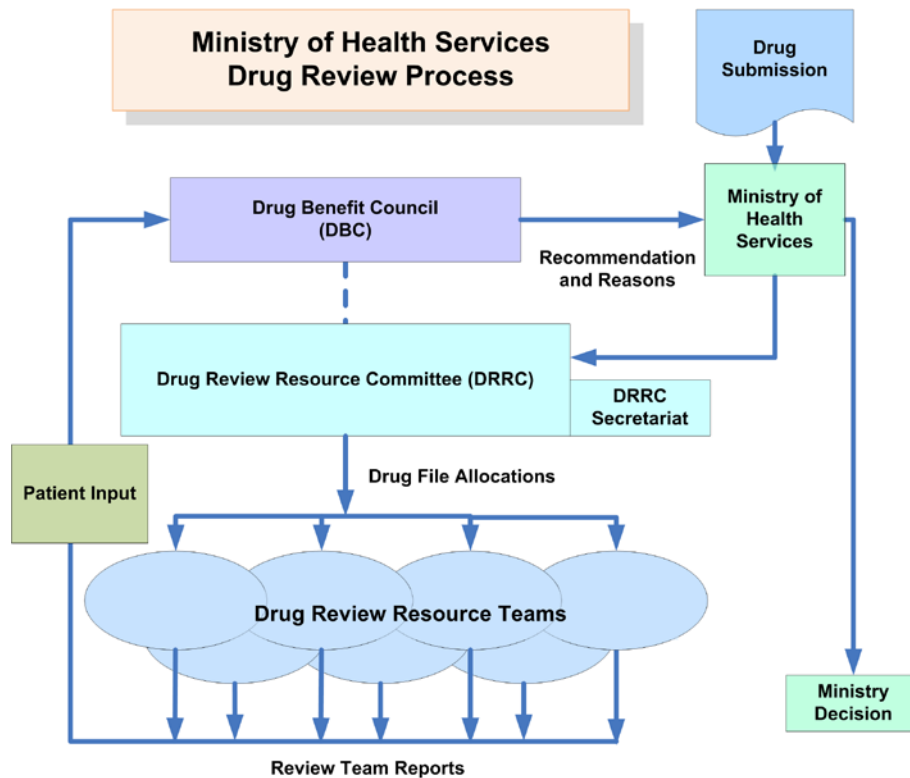
### ***Review Process Stages in British Columbia***

The review process in B.C. involves two entities: the Drug Benefit Council (DBC) and the Ministry of Health Services.

The DBC is an independent advisory committee made up of nine professional members with expertise in critical appraisal, medicine, ethics, pharmacy and health economics, and three members from the public. Their task is to review drug submissions and make recommendations to the Ministry.

More information on the DBC can be found on the PharmaCare website at [http://www.health.gov.bc.ca/pharmacare/formulary/dbc\\_info.html](http://www.health.gov.bc.ca/pharmacare/formulary/dbc_info.html).

The diagram below illustrates how the drug review process works.



### 1 - Drug Review Resource Committee (DRRC)

When the patented drug has gone through the necessary Health Canada and CDR reviews, the Ministry starts its review process. The Ministry sends the drug submission to the DRRC, a subcommittee of the DBC.

The DRRC establishes the review requirements, including requesting reports or other inputs required for each drug submission. The DRRC also assigns expert review teams, called Drug Review Resource Teams (DRRTs), to complete the required review reports for each drug submission.

Depending on what reviews have been done to date, requested reports may include clinical evidence, clinical practice and pharmaeconomic reviews.

### 2 - Drug Review Resource Teams (DRRT)

Each DRRT produces written reports on their assigned drug and forwards them to the drug sponsor for review. The drug sponsor can submit written comments for the DBC to consider during their review.<sup>3</sup>

### 3- Patient Input

The Ministry has implemented a process that lets British Columbia patients, caregivers and patient advocacy groups submit input on specific drug reviews. Learn more at [www.health.gov.bc.ca/pharmacare/yourvoice](http://www.health.gov.bc.ca/pharmacare/yourvoice).

<sup>3</sup> This is one of the four points at which stakeholders can become engaged in the review process; see [Sponsor Engagement in the Drug Review Process](#) for details.

## 4 – Drug Benefit Council (DBC) review

All DRRT reports, drug sponsor written comments, patient input and other review documents are forwarded to DBC members for review at their meetings. More information on the DBC can be found on the PharmaCare website at [www.health.gov.bc.ca/pharmacare/formulary/dbc\\_info.html](http://www.health.gov.bc.ca/pharmacare/formulary/dbc_info.html).

The DBC reviews all the documents and makes a recommendation to the Ministry about covering the drug under the PharmaCare program. The DBC recommendation includes:

- whether or not to cover the drug,
- how to cover the drug (i.e., a regular benefit for everyone or covered only under certain circumstances as a Limited Coverage benefit).

The DBC considers the following when making a recommendation:

- available information on the clinical effect of the drug and health outcomes
- whether it is good value for the people of British Columbia
- whether PharmaCare already covers a drug or drugs that work as well as this one
- clinical practice and ethical considerations
- the sponsor’s written comments on the DRRT review reports
- the recommendations of the national Common Drug Review, when applicable

## 5 – Ministry Decision

In making its drug listing decision, the Ministry considers:

- the DBC’s recommendation
- PharmaCare policy for this type of drug and other programs that exist in the Ministry
- which PharmaCare plans would cover the drug
- whether PharmaCare has the resources to cover the cost of the drug

# CONFLICT OF INTEREST GUIDELINES

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The Ministry is committed to a fair, independent, objective, and unbiased drug review process. All people who take part in the review of a drug submission, including members of the DBC, the DRRC, and the DRRTs, are held to the highest ethical standards when conducting their activities.

For this reason, all persons involved in the drug review process must declare any relationship they, or their immediate family, have that creates—or could appear to create – a conflict of interest<sup>4</sup>. The need to disclose conflict of interest information is ongoing and is the responsibility of all involved in the review process.

Examples of information that need to be disclosed include: payments or research funds received from a company that may benefit from the drug review decision; financial ownership in such a company; being employed by such a company; and any arrangement or relationship through which the participant could either earn or lose money because of a Ministry drug coverage decision.

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<sup>4</sup> Ministry guidelines for the drug review process state that “a conflict of interest may exist whenever a Participant or an Immediate Family Member of a Participant has a direct or indirect interest or relationship, financial or otherwise, with an Entity that may affect or reasonably appear to affect the objectivity or fairness of the Participant in the Drug Benefit Review Process.” ([www.health.gov.bc.ca/pharmacare/formulary/pdf/DBC-COI-Guidelines.pdf](http://www.health.gov.bc.ca/pharmacare/formulary/pdf/DBC-COI-Guidelines.pdf))

Individuals who declare possible conflict of interest information are not automatically excluded from participating in the drug review process.

Whether an individual is selected to participate or not depends upon the particular drug submission under review and is determined by the DBC and/or the DRRC. To select drug reviewers, the DRRC assesses the review requirements of the particular drug submission, the expertise of the potential reviewers, and the conflict of interest information declared by the reviewers. It is up to the DRRC to select the best reviewer without conflict of interest whenever possible. As such, the DRRC may select a reviewer with an identified conflict of interest after weighing the potential benefits and risks of including the participant in the review.

Full details on the Ministry's Conflict of Interest Guidelines and forms are on the PharmaCare website at [www.health.gov.bc.ca/pharmacare/formulary/pdf/DBC-COI-Guidelines.pdf](http://www.health.gov.bc.ca/pharmacare/formulary/pdf/DBC-COI-Guidelines.pdf).

## MINISTRY DRUG REVIEW TIMELINES

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When a drug needs a CDR review, the Ministry starts its own review process when the CDR process is complete, (i.e., **on the date when the CDR issues its final recommendation**).

All other patented drug submissions, start on the **date the complete submission is received by the Ministry**.

The Ministry has set specific target timelines in which to complete drug reviews. The target timeline to a decision (time-to-listing decision) is defined as the time from which the Ministry begins its review to the time that the Ministry publicly communicates its decision and usually includes completing all implementation steps.

The target timeline to a decision for a **standard review** is nine (9) months. The timeline for a **complex review** is twelve (12) months. A complex review usually includes extra requirements, such as having to develop clinical coverage criteria, develop a Special Authority form, complete discussions with a pharmaceutical manufacturer, and/or complete other implementation steps as required.

### Priority Reviews

A drug submission may be given priority status if it:

- was granted priority review status by CDR, or
- meets a significant clinical need and shows major therapeutic benefit, or
- shows substantial economic benefit

Priority drug reviews will be completed within six (6) months for standard submissions or nine (9) months for complex submissions. Further details on priority reviews are on the PharmaCare website at [www.health.gov.bc.ca/pharmacare/formulary/drugsubrev.html](http://www.health.gov.bc.ca/pharmacare/formulary/drugsubrev.html).

## FURTHER INFORMATION

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You can find more information about drug reviews and drug review results on the PharmaCare website. Visit these pages to find out about:

- [Drug Submission Requirements for Patented Drug Products](#)
- [Drug Benefit Council](#)
- [Conflict of Interest Guidelines](#)
- [Sponsor Engagement in the Drug Review Process](#)
- [Drug Review Results](#)