

# THE DRUG REVIEW PROCESS IN B.C. – OVERVIEW

The BC PharmaCare program has two main goals:

1. Cover drugs that support the health and well-being of British Columbians.
2. Make sure that the drugs PharmaCare covers are affordable and give the best value for money.

To meet the first goal, PharmaCare covers a drug only if it has a proven record of safety and effectiveness. To meet the second goal, PharmaCare compares each drug to the drugs it already covers that treat the same condition. For example, if more than one drug provides the same health benefit, PharmaCare may cover only the drug(s) that offers the best value.

Before PharmaCare decides if it will cover a drug, the drug goes through a review to find out if covering it aligns with the goals above. This helps to create a PharmaCare program that is fair, effective, and can meet the demands of the future.

## HOW DRUGS ARE REVIEWED IN CANADA AND B.C.

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In Canada, drug coverage reviews take place in three stages.

### STAGE 1 – FEDERAL GOVERNMENT – HEALTH CANADA

Before a manufacturer (often called the “drug submission sponsor”) can sell a drug in Canada, they must receive a Health Canada Notice of Compliance (NOC). Before issuing an NOC, Health Canada looks at the:

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

>>> To learn more, visit the [Health Canada drug review process](#) web page.

### STAGE 2 – NATIONAL REVIEW – COMMON DRUG REVIEW

If a manufacturer wants provincial drug plans to cover their drug, they send a drug submission to the Common Drug Review (CDR)<sup>1</sup>. The CDR is a national review process. It is managed by the Canadian Agency for Drugs and Technologies in Health (CADTH).

The CDR looks at:

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

A team of independent experts reviews each drug. They review the drug information and advise whether or not provincial plans should cover it. They make one of four recommendations: (1) Do not cover at all, (2) cover but only if the manufacturer lowers their price, (3) cover but only for certain patients or under certain conditions, and (4) cover as a regular benefit (that is, for all PharmaCare beneficiaries).

PharmaCare may negotiate with a manufacturer either at the provincial level or through the [pan-Canadian Pharmaceutical Alliance \(pCPA\)](#). Provinces and territories that participate in the pCPA work together to achieve better value for brand and generic drugs for publicly funded drug programs.

>>> To learn more, see the [CDR process](#) on the CADTH web page.

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<sup>1</sup> Except for Québec which uses a different drug review process.

## STAGE 3 – B.C. REVIEW – MINISTRY OF HEALTH PHARMACARE DRUG REVIEW

BC PharmaCare carries out its provincial review before making a drug coverage decision. This provincial review builds on the work done by Health Canada and the CDR process and makes sure the decision will be right for B.C. — it does not repeat work done by the CDR.

There are three steps in the provincial review: (1) gather information and input, (2) obtain a recommendation from the Drug Benefit Council (DBC), and (3) make a final PharmaCare coverage decision. However, if the CDR recommends that provincial plans should not cover the drug at all, the DBC usually will not review the drug; in these cases, the final PharmaCare decision is based largely on the CDR recommendation and input.

### (1) Gather information and input

This step is vital in making sound drug coverage decisions. The information gathered is specific to the needs of the review and may include, but is not limited, to:

- information on a drug’s safety and clinical benefits,
- information on value for money,
- the effect of current PharmaCare coverage policies,
- potential affect on the PharmaCare budget,
- input from practicing B.C. clinicians, including family physicians and specialists,
- input from B.C. residents who may be affected by a coverage decision, and
- input from the manufacturer about the CDR recommendation (if applicable).

### (2) Obtain the Drug Benefit Council recommendation

The DBC is an independent advisory committee. It has 12 members; 9 experts in critical appraisal of medical reports, medicine, ethics, pharmacy and health economics, and 3 members of the public. When the CDR recommends covering a drug, the DBC reviews all the information and input that has been gathered. It then recommends whether or not PharmaCare should cover it and/or how it should cover it. For example, a drug might be covered as a regular benefit for all PharmaCare beneficiaries or as a “limited coverage” benefit for people in specific medical circumstances.

>>> To learn more, visit the [DBC web page](#).

### (3) Make a final decision

The final PharmaCare decision is made after the federal, national, and DBC reviews are complete. The decision considers the following:

- the CDR recommendation (if there was one),
- the DBC recommendation (if there was one),
- manufacturer input and engagement,
- PharmaCare policy and plans for this type of drug, and any other Ministry programs, and
- whether PharmaCare has the funds to cover the cost of the drug.

## KEEPING IT FAIR

PharmaCare is committed to a fair, independent, objective, and unbiased drug review process. Everyone who takes part in a review is held to the highest ethical standards. Each participant must declare any relationship they, or their immediate family, have that creates—or could appear to create—a conflict of interest that could affect their input. (For example, if someone owns shares in a company that makes a drug that is being reviewed, they might be influenced by the possibility of financial gain.) People with a possible conflict of interest may still take part in the review process but their conflict of interest will be taken into account when evaluating their input.

>>> To learn more, see [Conflict of Interest Guidelines](#).

### *Who can give input to drug reviews?*

PharmaCare welcomes input from:

- any B.C. resident who has the illness or condition that a drug will be used to treat,
- their caregivers,
- B.C. patient advocacy groups that represent B.C. residents who have the illness or condition, and
- practicing B.C. clinicians with specific expertise with the drug or the illness it is used to treat,
- manufacturers/drug submission sponsors

>>> *Patients, caregivers and patient groups should visit [Your Voice](#).*

>>> *Clinicians should visit the [Clinical Practice Reviewer Reports](#) web page.*

>>> *Manufacturers/drug submission sponsors should visit the [Drug Sponsor Engagement](#) web page.*