

THE DRUG REVIEW PROCESS IN B.C. – OVERVIEW

The B.C. 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 full review to find out if covering it aligns with the goals above. This helps create a PharmaCare program that is fair, effective, and that can meet the demands of the future.

HOW DRUGS ARE REVIEWED IN CANADA AND B.C.

In Canada, drug 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 – 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)¹. 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 review each drug. They study 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).

>>> Learn more about the [CDR process](#) on the CADTH website.

¹ Except for Quebec, which uses a different drug review process.

STAGE 3 – B.C. 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 by Health Canada and the CDR, and makes sure the decision will be right for B.C. It does not repeat work done by the CDR.

The provincial review has three steps: (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 effect 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 have 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.

(3) Make a final decision

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

- 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 their input is evaluated.

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

Who can give input?

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;
- practicing B.C. clinicians with specific expertise with the drug or the illness it is used to treat; and
- manufacturers/drug submission sponsors.

>>> Patients and caregivers can learn more at [Your Voice](#).

>>> Clinicians and manufacturers should visit [Health Industry Professionals](#).